# INTERFACE PRESSURE AND STRESS DISTRIBUTION IN PROSTHETIC FITTING[a]

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## INTRODUCTION

The research described herein is intended to extend the level of understanding of lower-extremity prosthetic aids which will eventually lead to improving the quality of application. Much time and effort have been spent on improving prosthetic fit and standardizing fabrication procedures (2, 3) in an attempt to restore normal gait. This particular work studies the basic mechanism affecting fit, i.e., associated pressure patterns and their variation with respect to time.

### New Fitting Techniques

The phrase "comfortable fit" as applied to prosthetic aids is more a concept than a definition. A suitable objective definition for "comfortable fit" has not evolved. The recognition of variables, their individual orders of magnitude, and the amount they contribute to this concept would greatly enhance the fitting and alignment of prostheses. In addition, they would provide a basis on which to improve existing technology as applied in clinical practice. Within the last 10 years, and since the publication of "The Manual of Below-Knee Prosthetics," (3) the application and use of total-contact patellar-tendon-bearing below-knee prosthetics has undergone some dramatic changes. New techniques of load-bearing and suspension (4) are in practice today and more are under development. The soft liner socket, so widely accepted a few years back, is now being challenged by such new concepts as the hard-

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shell socket with soft distal end pad, the air-cushion sockets, and the water-filled socket. The supracondylar strap suspension is also being challenged by the supracondylar wedge and the extended shell suprapatellar support. In the weight-bearing mechanism, one notices a wide difference of opinion in the techniques employed to obtain desired results. Whether one should attempt to transfer load in particular regions of the stump or to uniformly distribute the load on the stump is highly dependent upon hypotheses rather than fact. The occasional failure to accommodate a patient with a patellar-tendon-bearing prosthesis may be a problem of poor execution rather than concept. This inability may result from a poor socket or a poor alignment. It is believed that the parameters causing physiological stump damage are normal stress (pressure) and shear stress at the interface between the prosthesis and the limb.

The measurement and display of this three-dimensional stress profile in time present an interesting engineering evaluation with definite physiological implications. Other instrumentation and data reduction schemes have shown a need to present the data in a meaningful manner to the physician. This research presents a new approach which emphasizes the visualization of the phenomena at the interface rather than individual numbers representing pressure values.

## Previous and Concurrent Studies

Various investigators have been interested in measuring and explaining normal stress between the body and a supporting surface. Most attempts have been more an exercise in explaining pressure at a point as a function of time, rather than display of pressure on a surface as a function of time. Muller, Hettinger, and Himmellmann (5) measured dynamic pressures between an above-knee prosthesis and a stump. These results are based on pneumatic transducers which recorded pressures over relatively large areas of the order of 25 square centimeters.

In 1962, G. Boni (4) published results of his attempts to record the pressure patterns between a stump and a socket. His work was not limited to lower-extremity prosthetics, as he worked primarily with below-elbow amputees. The preliminary portion of his work was the determination of the type of transducer to be used. The choices involved a conventional strain-gage bridge, capacitance bridge, a piezoelectric crystal, or a magnetic inductance transducer. His preliminary experiments led to the development of a new transducer which consisted essentially of two silver electrodes separated by a layer of conductive rubber containing numerous holes. The electrodes and the layer of rubber were bonded and the holes in the rubber filled with microphonic granules. This composite was covered with a layer of continuous rubber.

The transducer was relatively large, 9/16 in. diameter and 1 in. thick. A second transducer was made with a conventional strain gage affixed to a thin steel blade. This thin steel blade acted as a diaphragm and was riveted to a second blade which acted as a support. The size of this transducer was ½ in. by 1⅛ in. The result of the experimental work showed both transducers were suitable for socket fit analysis, but the strain-gage transducers were preferable.

At Case Western Reserve University, a pneumatic cell was developed to record static pressure profiles (7,8,9). This multicellular pad was used to measure pressure distributions between a patient and a wheelchair. It was basically a binary procedure utilizing stepwise changes in pressure level. Although quite successful, it could not be used to measure time-varying distributions with ease. The technique does not lend itself to the complicated geometry of the leg.

Work has been conducted at New York University recording the interface pressure in above-knee prostheses (10). The work involved permanently positioned transducers, flush-mounted in the prosthesis wall. The time-continuous pressure transducers are capable of measuring dynamic changes. In this work, 25 transducers were mounted in the wall and brim of the test socket of a single above-knee amputee. These transducers were designed and developed at New York University and were built into the prosthesis at the time of its construction. The transducers could be removed from the prosthesis at any time by inserting a dummy plug after its removal. The results of the suction socket studies showed a pressure range from −1 p.s.i.g. to 24 p.s.i.g. during normal gait. It was also found that large diurnal variations in socket pressure occurred particularly in the brim. It was felt that this difference in pressure could amount to 10 percent from day-to-day. It was also observed that pressure variations resulting from abduction and adduction of the shank through a 2-deg. angular change generally were small. They showed that the pressures developed during walking were higher than those experienced during stance.

Work is being conducted at Baylor University (4) measuring interface pressure on above- and below-knee prostheses. The purpose of this work is to develop a method for the quantitative and kinesiological evaluation of prosthetic fit and gait analysis in the above-knee and/or below-knee amputee and to apply this method to a series of patients in clinical and vocational followup programs. They intended to quantify the characteristics of gait and prosthetic fit in successfully rehabilitated amputees, and compare these "normal" patterns with the unsuccessfully fitted amputees. The areas of interest are the pressures on the ischial seat, the lateral aspect of the socket, and the distal tissues. Combining this information with goniograms of the prosthetic and anatomical knees and with event markers attached to both shoes, they hope to obtain a quantitative evaluation of prosthetic fit and gait analysis in amputees. They also feel that a recording of skin temperature on both limbs would provide significant information. Their present system includes a multichannel analog magnetic tape recorder and a small computer connected in parallel for controlled data acquisition and storage on IBM compatible digital tape. It is intended that this digital tape can be further processed on larger computer systems located within that university.

## Problem Definition

In the work conducted thus far, the investigators have faced two serious problems. The first was the transducer itself. It was either too bulky or too fragile. The second problem was that all recordings were made in analog form which presented a tremendous data reduction problem. At the prosthesis interface, both pressure [normal stress] and shear stress are present. Thus far, no one has attempted to record shear stress. This problem presents a unique instrumentation dilemma since all the criteria of size, sensitivity, etc., for the pressure transducer are necessary for the shear stress transducer except that the shear stress transducer must also indicate direction. At the basic level suggested by the previous investigators and this author, a general problem statement might be,

> "Measure and display normal pressure and shear stress distributions as continuous functions in geometry and time at the interface between a below-knee prosthesis and skin tissue."

The general problem statement is a comprehensive evaluation of the prosthesis-tissue interface. From an economic viewpoint, insertion of transducers to totally cover the interface could easily become prohibitive. It was decided, for purposes of economy, to test only one section of the stump at a time rather than the entire surface. Although pressure transducers are commercially available, no shear-strain indicating instrument was available. It was this reasoning that led to the decision not to record shear stress now but to concentrate efforts on the pressure recording. The problem was then defined as follows:

> "Measure and display normal pressure distributions as continuous functions in geometry and time at a portion of the interface between a total-contact below-knee prosthesis and skin tissue."

## Similar Research at Other Centers

Since two other organizations, Baylor University and New York University, concurrently were conducting research on pressure studies in either above- or below-knee prosthetics, communication was maintained with these groups for the purpose of sharing techniques and eliminating overlap in experiments or methodology, while augmenting each other's work with as much common technology as possible.

## ANATOMIC COORDINATE SYSTEMS

### The Anatomic Problem

At the University of Michigan, with rare exceptions, below-knee prostheses are patellar-tendon-bearing. Most cases involve recent amputations, and the prostheses have soft liner inserts so that the socket can easily be modified to compensate for shrinkage of the stump. The amount of "end-bearing" depends on the reason for the amputation, condition of the stump, and patient comfort.

The solid-ankle-cushion-heel foot [SACH foot] is used with patellar-tendon-bearing prostheses, with few exceptions. Sidebars and corset are applied to the initial prosthesis, and supracondylar suspension is usually prescribed for subsequent artificial limbs. Pressure-tolerant and pressure-sensitive areas have been defined (Fig. 1), but pressure levels and distributions have not been defined. These pressure profiles are influenced by a combination of factors. The more important of these are (2):

1. Socket geometry
2. Socket alignment
3. Geometrical relationship of the socket to the foot
4. External influences of the thigh corset and side joints

The biomechanics of the below-knee prosthesis describing the force distribution for below-knee prostheses was presented in some detail in the patellar-tendon-bearing below-knee prosthesis manual (2) published in 1961. This simplified analysis shows the forces resulting from the interface pressure distributions. Although this study is conceptual, it exemplifies the complex form that the interface pressure distribution must display.

### A Proposed Coordinate System for a Below-Knee Stump

The anatomic frame of reference previously defined was neither convenient nor precise enough for the purpose at hand. A frame of reference oriented to a specifically defined kick-point instead of an area in the general region of the distal end of the tibia appeared to be essential. Four transducers were arranged in a ½-in.-sq. matrix with a fifth transducer at the center. With a precise system of coordinates it was possible to discriminate between individual transducers for one layout or position of the matrix. By overlay of subsequent and adjacent layouts it was possible

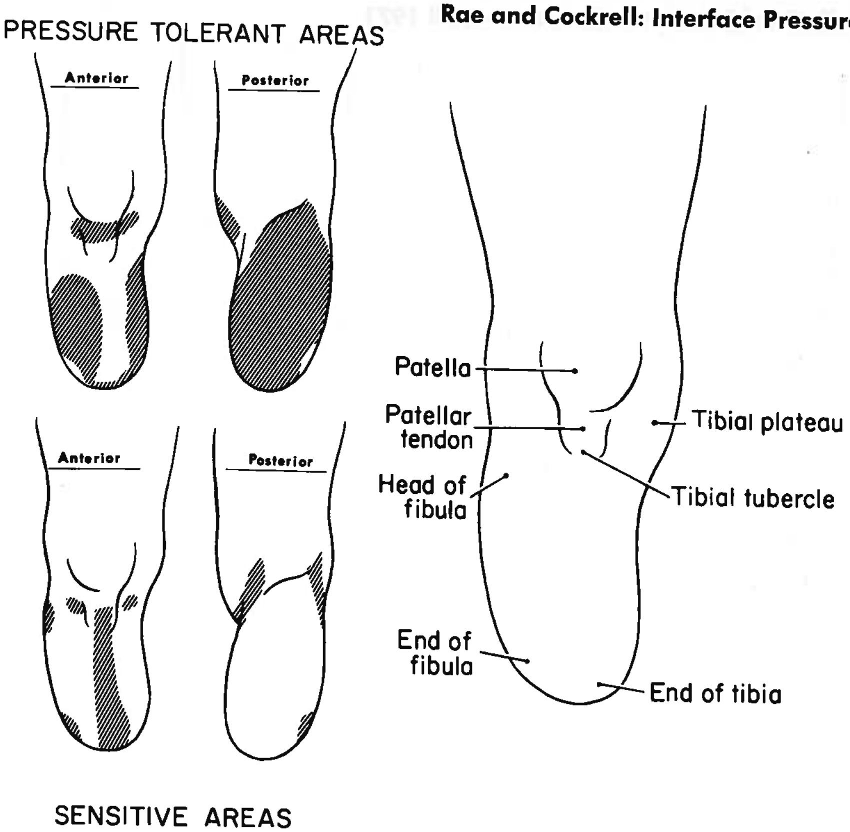


FIGURE 1.—Pressure tolerant and sensitive areas with anatomical reference points.

to relate pressure readings from one layout to the next as well. The necessity for a precisely located coordinate system as a frame of reference existed for the patellar region also.

A more precise coordinate system was defined utilizing existing terminology and reference points as much as possible. The philosophy was to define anatomical points and recognize perturbations from these points rather than define an absolute coordinate system for the stump. This would compensate for variations in stump sizes and shapes and its accuracy would be in direct proportion to the magnitude of the perturbation from a point. Since one of the primary areas of interest in this research was the distal end of the stump, this required a precise definition of the kick-point. Figure 2 is a lateral view of the anterior-posterior plane showing the relationship of the tibia, fibula, and epidermal tissue.

The kick-point was defined as the point on the tibia where the bevel occurred on the anterior crest and was transferred to the skin tissue. This point was found by palpating the stump. The anterior crest of the tibia is easily traced to the point where the crest breaks into the bevel. The

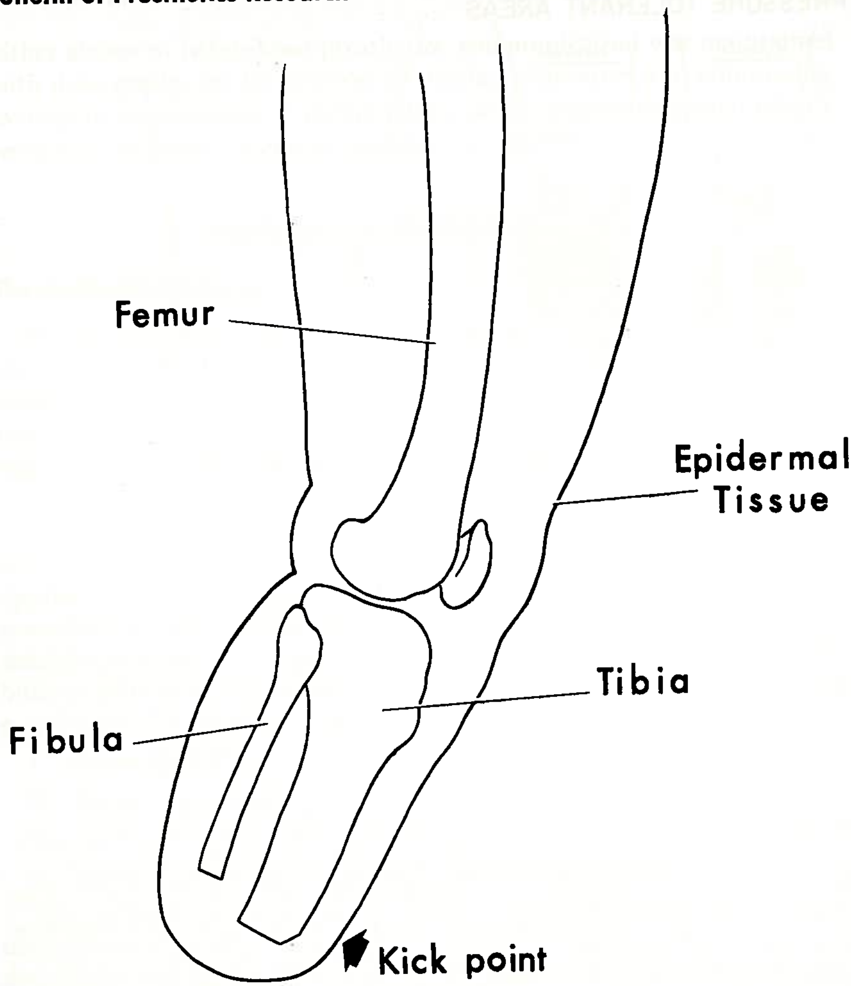


FIGURE 2.—Lateral view of the A-P plane showing bone relationships after surgery.

point was then marked on the skin and used as the origin for the coordinate system (Fig. 3). It is certainly true that under loading this point may shift because of the relative movement of the skin in relation to the tibia, but we are unable to locate this point by direct measurement once the prosthesis has been applied. With the point located, there was now a need for orthogonal X and Y coordinates from which to measure grid locations. For the +Y coordinate, a line is traced up the anterior crest of the tibia from the kick-point. The +X coordinate is orthogonally perpendicular to the Y axis at the kick-point and runs circumferentially in the lateral direction around the distal end of the stump.

With the kick-point and coordinates defined in the unloaded condition, it was now possible to define a pattern of transducer grids refer-

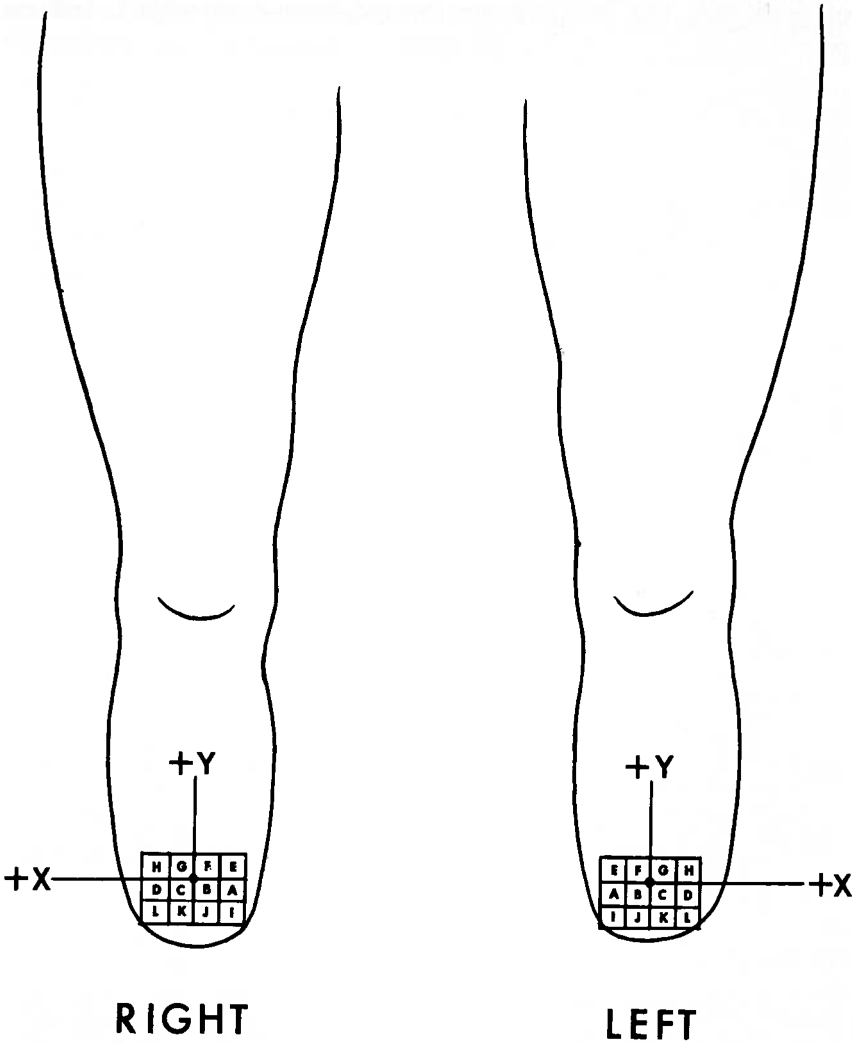


FIGURE 3.—Kick-point zone definitions for both right and left amputations (anterior view).

enced to the coordinate system. Zones with dimensions of ½ in. by ½ in. were located and named. The first such area was placed two zone-widths in the +X direction from the origin as shown in Figure 3 and was called Kick-Point Zone A. Kick-Point B was located ½ in. laterally from Zone A. Kick-Point Zone C was placed ½ in. laterally beyond Zone B. Zone D followed Zone C to complete one row. Just above the row reading from A to D was a second row of four zones reading from E through H. Below the A to D row was a third row of four zones designated I through L. Thus the total pattern consisted of a matrix of three rows and four columns lettered from A through L and expandable in either or both directions.

This same nomenclature of zones could be applied to any area having an anatomic structure resolvable to a point. In the case of the patella, the same method of nomenclature was applied. The patellar point was located at the intersection of the anterior crest of the tibia and the base of the patella. This is shown in Figure 4.

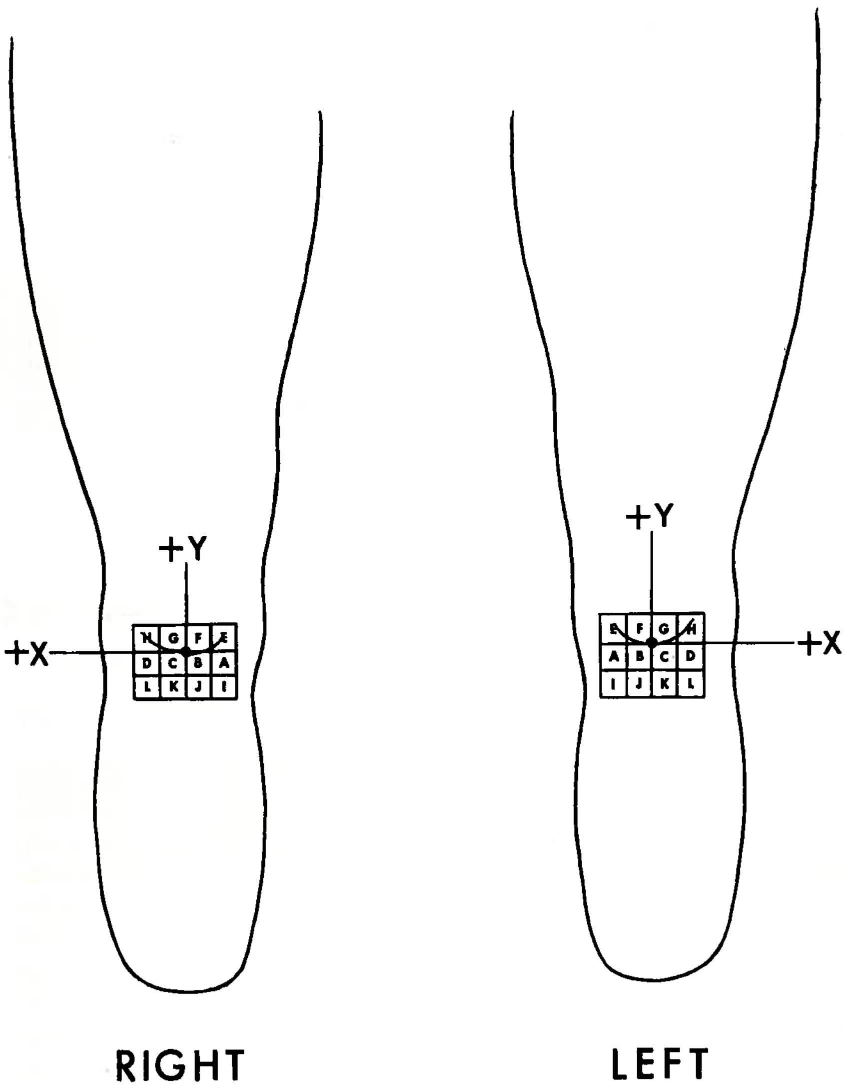


FIGURE 4.—Location of the patellar point and zone definition (anterior view).

Since these geometric points can be transferred from one stump to another and the perturbations from these points do not represent large dimensions when compared to the nominal stump dimensions, it is anticipated that the results may be comparable from one patient to another in general form. If not, these geometrical areas should be reproducible from one experimenter to another on the same patient and the phenomena occurring within the area can be scrutinized for repeatability.

## THE HARDWARE SYSTEM

The experimental work falls logically into two divisions: the selection of sensing elements that will measure the experimental quantities and the treatment of the signal from the transducer so that effective use can be made of the information collected. On the basis of experience reported by previous investigators, the following represent the criteria for overall performance of the whole system:

1. A pressure transducer with minimal sensing area and volume
2. Flexibility in positioning the transducer on the body
3. Ability to measure the pressure in regions of small radius of curvature with a reasonable degree of accuracy
4. Ability to gather multichannel data with ease
5. Ability to calculate results from the information gathered with ease
6. Ability to present the data efficiently to either a medical or engineering audience.

The system finally selected utilizes a Linc-8 laboratory computer (Digital Equipment Corporation) having eight analog channels to receive the experimental data. This computer is a dual-processor, 12-bit machine having 4,096 words of core-memory. In addition it is equipped with an ASR-33 teletype, dual magnetic transports and a 5-in. Tektronix 561 oscilloscope. The eight analog channels as well as six sense lines can be sampled under program control and represent the primary inputs to the system while taking pressure data. Control, remote from the machine using these features, was achieved to provide coordination with the experimental procedures.

The eight available data channels were appointed as follows:

5—analog pressure

2—hip and knee positions

1—foot-floor contacts

**The Pressure Transducer**

Since it was not the intent of this investigation to completely develop a pressure transducer, commercial products were surveyed to find the smallest transducer available. At the outset the transducer manufactured by Scientific Advances, Inc., met the criterion of size. It is a strain-gage diaphragm-operated transducer originally intended to record dynamic pressure on helicopter blades (Fig. 5).

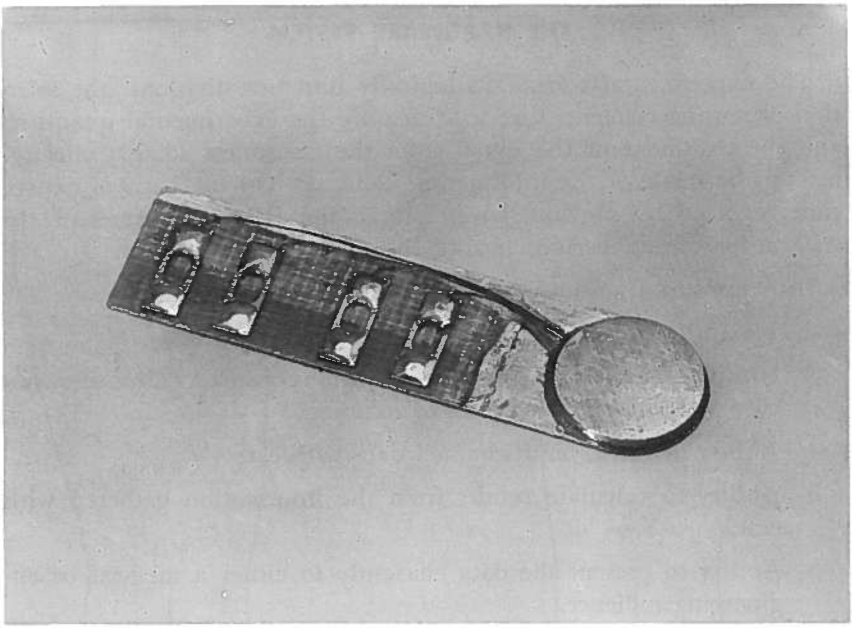

FIGURE 5.—Scientific Advances, Inc., M-7F Series 100 p.s.i. pressure transducer.

Two of these transducers were purchased and installed in a below-knee prosthesis and some preliminary determinations made. Results indicated that the transducer responded reasonably well to the environment and that the sizing was approximately correct. Serious questions arose regarding the use of the transducer on or around bony prominences within the stump. The radii of curvature at the kick-point, condylar flares, and medial and lateral plateaus of the tibia led to questions of applicability of the transducer in these regions. Since no transducer was available that would provide complete adaptation to the curvature of the stump, the problems of complex geometry were solved by instrumentation techniques rather than by the development of any new transducer. With this provision the transducer was judged acceptable for the purpose of obtaining the pressure information. An active search for a smaller and less expensive transducer was maintained. In particular, contact was made with Kulite Semiconductor Products, Inc., where the transducer shown in Figure 6 was produced. This transducer incorporates a monolithic integrated-circuit Wheatstone bridge formed directly on a silicon diaphragm. It was also developed for measurements of dynamic surface pressure on such structures as helicopter and turbine blades or air foils.

Table 1 gives the specifications for both of these transducers.

TABLE 1.—*Comparison of Kulite and Scientific Advances Transducers*

| Specification | Kulite LPS-125-500 | Scientific advances M-7F-100 |
|---|---|---|
| Diameter | 0.125 in. | 0.250 in. |
| Thickness | 0.030 in. max. | 0.027 in. max. |
| Internal pressure | —(sealed) | —(sealed) |
| Pressure range | 0–500 p.s.i.a. | 0–100 p.s.i.a. |
| Natural frequency | 350 KHz | — |
| Overpressure | 100% F.S. | 25% F.S. |
| Excitation | 5 VDC or ACRMS | 3 VDC or ACRMS |
| Impedance (nom.) | 350 ohms | 120 ohms |
| Zero balance | ±3% F.S. max. | — |
| Sensitivity (nom.) | 0.05 mv./v./p.s.i. | 0.01 mv./v./p.s.i. |
| Temperature effect on zero | ±0.02% F.S./°F. | ±0.2% F.S./°F. |
| Temperature effect on sensitivity | ±0.03% F.S./°F. | ±0.08% F.S./°F. |
| Nonlinearity and hysteresis | ±1.0% F.S. | ±0.5% F.S. |
| Repeatability | ±0.2% F.S. | ±0.25% F.S. |

The transducers in the forms shown in Figures 5 and 6 were unacceptable for one basic reason: the mechanical lead connection and terminal strip lacked the strength required to operate durably in a prosthesis. The possibility of working with the Kulite Corporation to alter their transducer to meet the need was investigated. Since they were agreeable, this was done.

In order to use a ribbon-cable conductor as an integral part of the transducer and to strengthen the mechanical connection, alterations were made to develop the transducer as shown in Figure 7. This transducer retains all the attributes of the original transducer while providing increased mechanical strength at the terminal connection. As can be seen in the figure, the temperature compensation network has been removed from the terminal pad, and the ribbon-cable overlies the paddle. After soldering, the entire connection was fixed in epoxy resin and the temperature compensation network installed at the other end of the ribbon-cable.

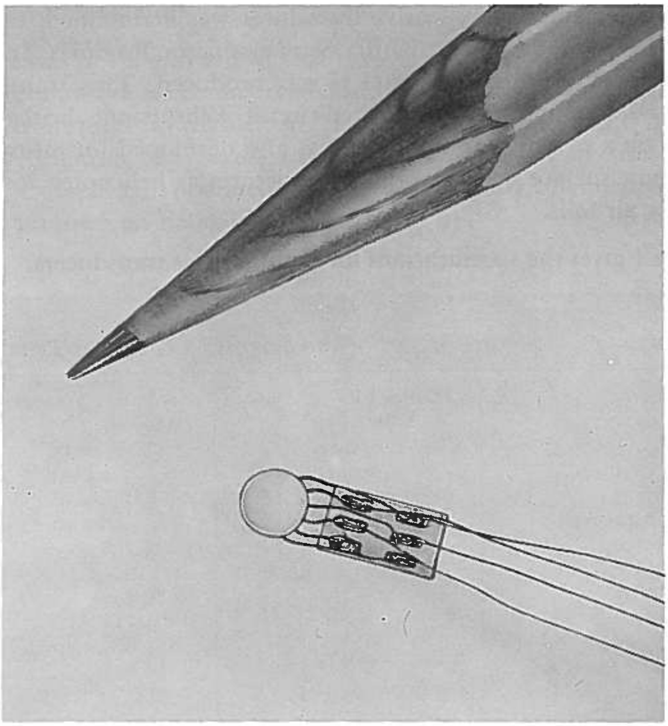

FIGURE 6.—Kulite Semiconductor Products, Inc., LPS Series transducer.

*Acceptance Tests*

When it was decided that the modified transducer would serve for the experimental work, a 100 p.s.i. unit was ordered. Acceptance was based on a shock test and thermal drift of zero.

The following procedure was adopted: The transducer was inserted between the heel and sock of a 120-lb. person, the shoe was replaced, and the transducer was then jumped on. Although this produces shock loadings, preliminary investigation had indicated that such pressures might well be produced with a below-knee prosthesis. In addition, the instrumentation for measuring temperature effect on zero was tested. Since this is a semiconductor device, assurance had to be provided that variation in skin temperature after insertion would not seriously impair the output of the transducer. In view of the type of calculation to be executed on the data, it was decided that the 3 percent zero drift that resulted was acceptable. It should be noted that use of the transducer at less than the rated pressure range increases the transducer sensitivity to temperature changes proportionately. The 100 p.s.i. unit failed to pass the impact loading tests. With transducer costs as a major factor and zero drift not so critical, a 500 p.s.i. unit was ordered. This transducer met

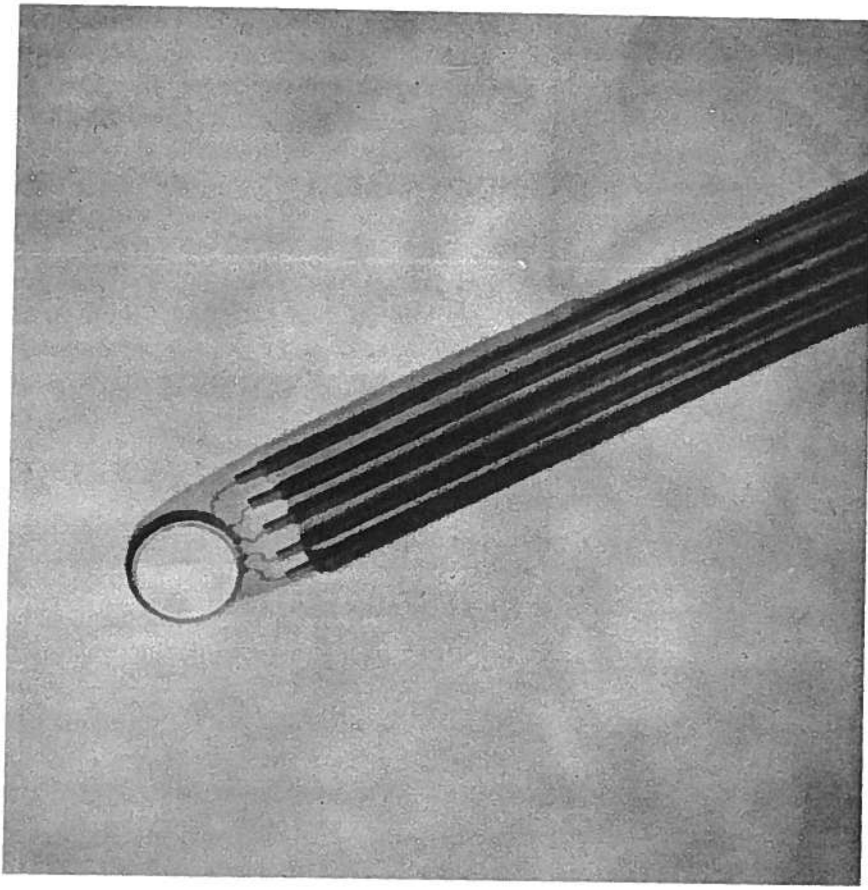

FIGURE 7.—Altered Kulite pressure transducer.

acceptance criteria and was inserted in a below-knee prosthesis. The subject chosen had a highly atrophied 25-year-old stump which exhibited numerous bony prominences and little soft tissue. The transducer was found acceptable for use in all the precarious regions that were anticipated. At this point in the investigation the remaining transducers needed for the study were ordered.

After receiving the transducers, it was found that the manufacturer had used bare copper ribbon-cable for attachment to the transducer, as well as a corrosive flux that wicked by capillary action between the wire and insulation. The result was that the cable in turn corroded and oxidized the AWG-34 wire (consisting of 40 strands of Number 50 wire) and broke electrical contact. The fault was identified after considerable study of the manufacturing processes for both the wire and the transducer. At this point the transducer manufacturer replaced the previous transducers with transducers constructed of silver-plated wire, which obviated all corrosion and oxidation problems and thus became the final form of the transducer used in all experimental work.

*Calibration*

The pressure range involved in the studies was estimated to be 0–200 p.s.i.g. The manufacturer was requested to supply calibration data for each transducer at 0, 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 125, 150, 175, and 200 p.s.i.g. Since each transducer shows some nonlinearity and a slightly different sensitivity, the calibration was checked with all signal conditioning attached, and the results actually represent a total-system calibration. The pressure vessel used for this testing was the valve body from an air regulator. The gas used was carbon dioxide, and the pressure indicator was a bourdon-tube dial indicator calibrated against a dead-weight testing unit.

*Pressure Transducer Format*

Five pressure transducers were used simultaneously, the number of transducers being related directly to the recording equipment. The transducer information could be used in at least two distinct manners. First, if five transducers were placed in a square matrix, the discrete information at any fixed time could be expanded mathematically to a two-directional one-pressure dimension curve. In this manner a pressure surface could be reproduced by curve-fitting the data. The matrix used (Fig. 8) was sandwiched in place by tape [Blenderm surgical tape, Number 1525, 1½ in. wide]. In turn, this tape could be applied to a stump at a test area. This matrix is a ½-in. square with the fifth transducer at the geometric center. The transducers are shown applied to a limb in Figure 9.

The second experimental layout was a linear array with the transducers in a straight line ½ in. apart and the taping scheme the same as before. This layout is shown in Figure 10. Figure 11 shows this layout applied to a limb. In this instance, the discrete pressure information is interpolated in one spatial dimension to form a curve. Figure 12 shows the composite transducer array and cabling.

*Signal Treatment—Pressure Channels*

Low level signal conditioning was accomplished using Daytronic Model 601B units having isolated bridge power supplies and bridge balance circuits. Hewlett-Packard Type 8875A differential data amplifiers having variable gain settings from 1 to 1,000 and upper band-limit filtering capability from 2 to 20 KHz, provided the analog signal multiplification needed for the pressure channels.

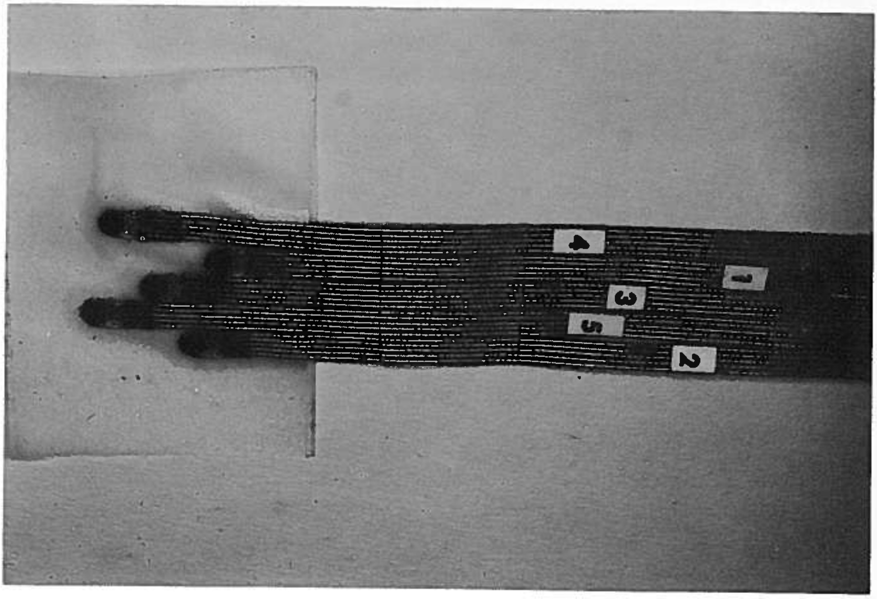

FIGURE 8.—Pressure transducers in an area array.

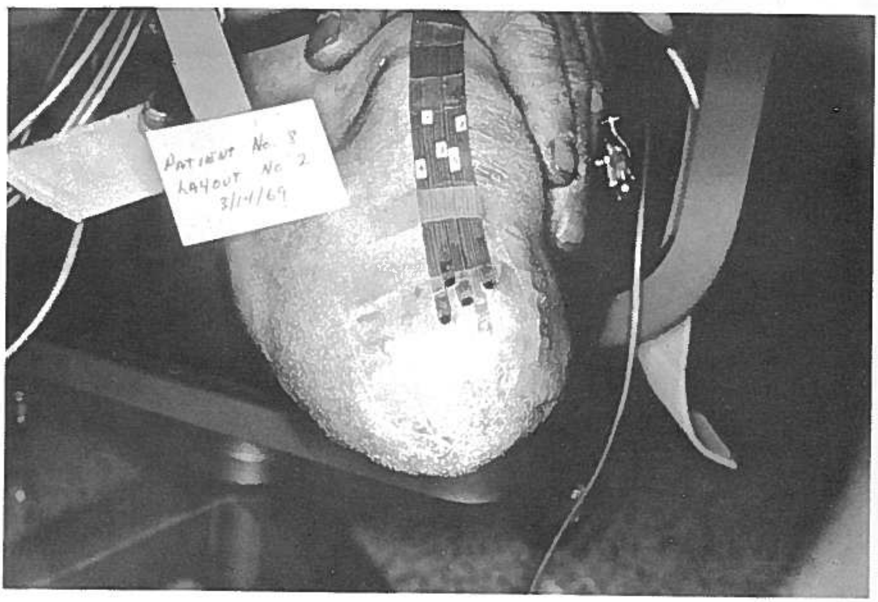


FIGURE 9.—Pressure transducers in an area array applied to a limb.

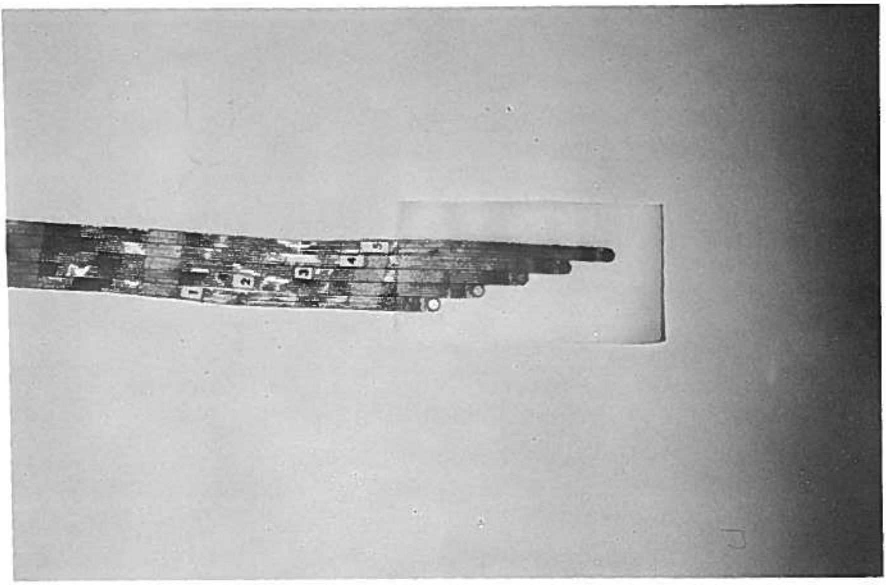

FIGURE 10.—Pressure transducers in a linear array.

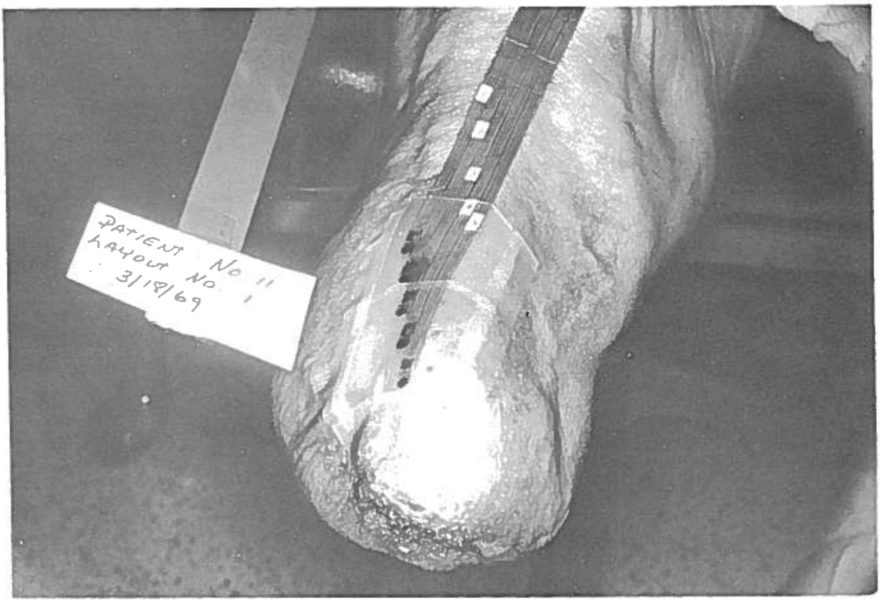


FIGURE 11.—Pressure transducers in a linear array applied to a limb.

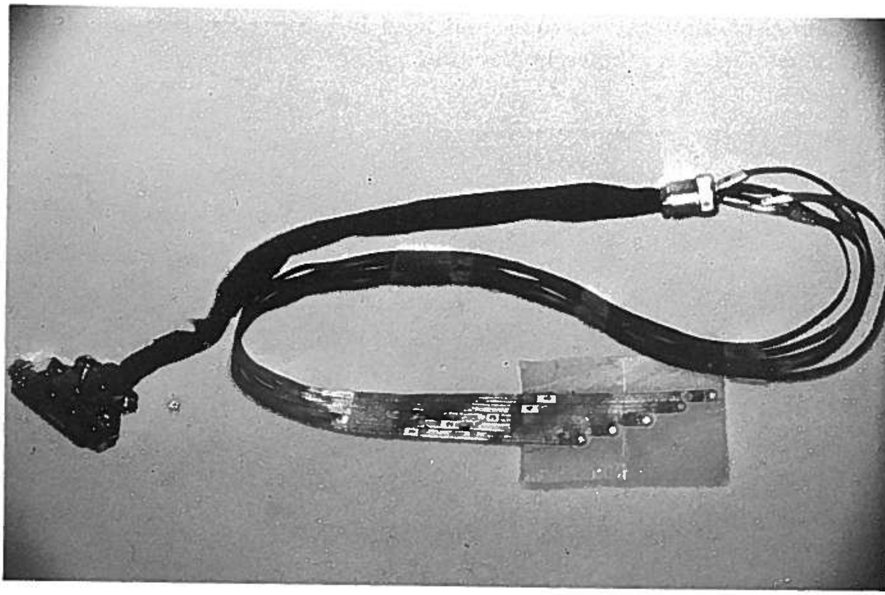

FIGURE 12.—Pressure transducer array and cabling.

*Knee and Hip Goniometers*

Goniometers were required in order to record the angular positions of the knee and hip during walking. These units and adapting hardware are shown in Figures 13 and 14. Matching 1,000-ohm potentiometers were mounted in the control panel, and output was read across the center taps of the two potentiometers. The control-panel potentiometer provided zeroing capability.

The power supply for the potentiometers was a ±15-volt common supply mounted in the control panel where the output signal was stepped down to provide a ±1-volt signal.

*Foot Switches*

Foot switches are electrical contacts mounted in various positions directly on the heel and sole of the shoe to indicate where the foot was in relation to the floor. The research group at Baylor University had approached the same problem and had tried to use a commercially available ribbon switch. They eventually manufactured switches of their own, using shim stock separated by sponge rubber. In their work, they were attempting to provide timing marks for computation of interval sizes during gait. They initially used five switches on the bottom of the shoe, but eventually reduced this to three.

On the basis of their experience, switches were fabricated from .010 in. brass shim stock and wired in a resistive network to provide a single channel of information, the signal level indicating the switches closed. These switches are shown in place in Figure 15.

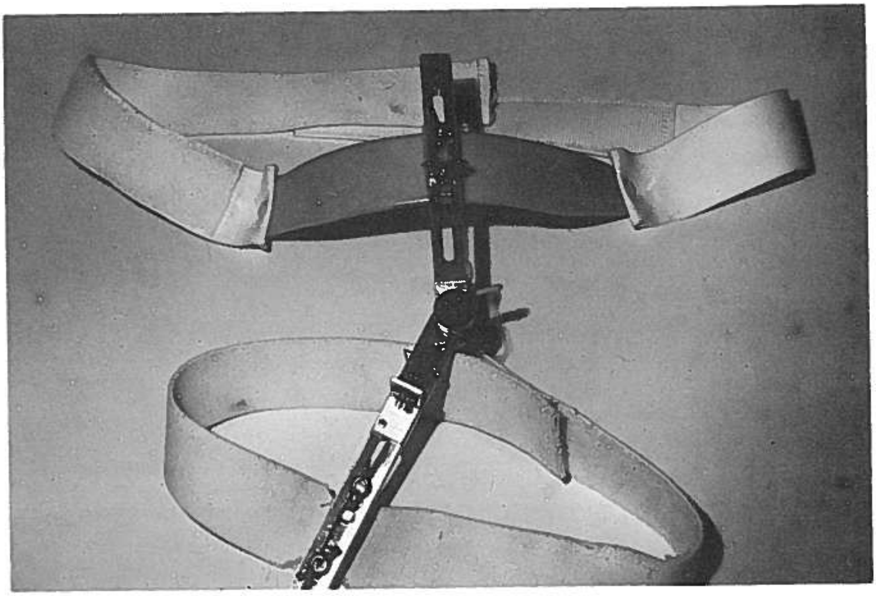

FIGURE 13.—Hip goniometer and adapting hardware.

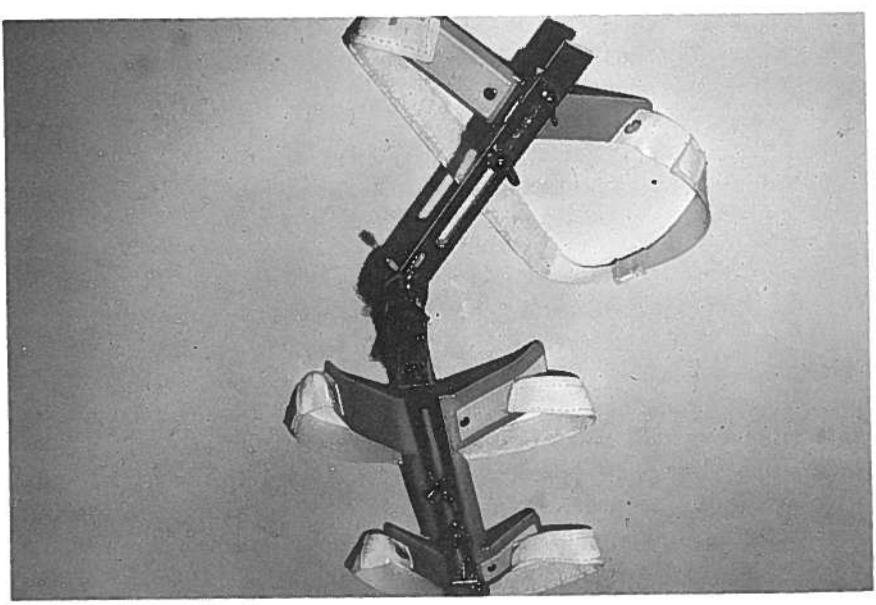

FIGURE 14.—Knee goniometer and adapting hardware.

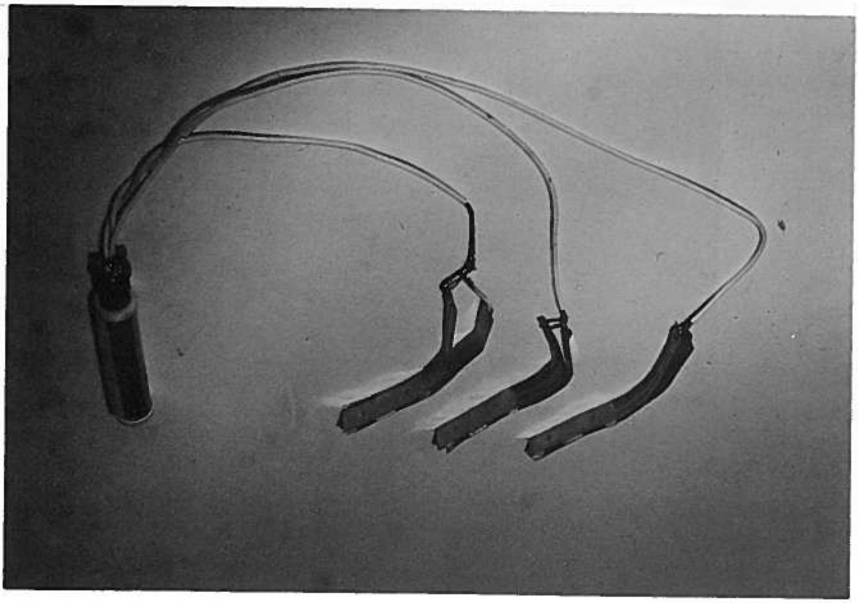

FIGURE 15.—Fabricated foot switches and connector.

*Control Panel*

With eight channels of information, it was necessary to assemble the active elements of signal control and output control in some manner. This was done by housing all the elements in a master control panel that provided the following conditions:

1. Central processing of all signal conditioning and amplification
2. Source of necessary power
3. A central place for the connection of all input and output cabling
4. A convenient means for the parallel output of resultant signals to as many recorders as necessary
5. A simple way to control all recording equipment as well as to monitor the status of the equipment.

For the basic rack we used an Ingersoll Products IEII assembly with casters. The slanted front panel was divided into three sections: The lower section housed the differential amplifiers; the center section housed the signal conditioners; the upper section contained hip and knee balance potentiometers and stepdown amplifiers, main power switch, recording indicator lights and switches, and two automatic ranging voltmeters which could read any individual channel. The control panel assembly is shown in Figure 16.

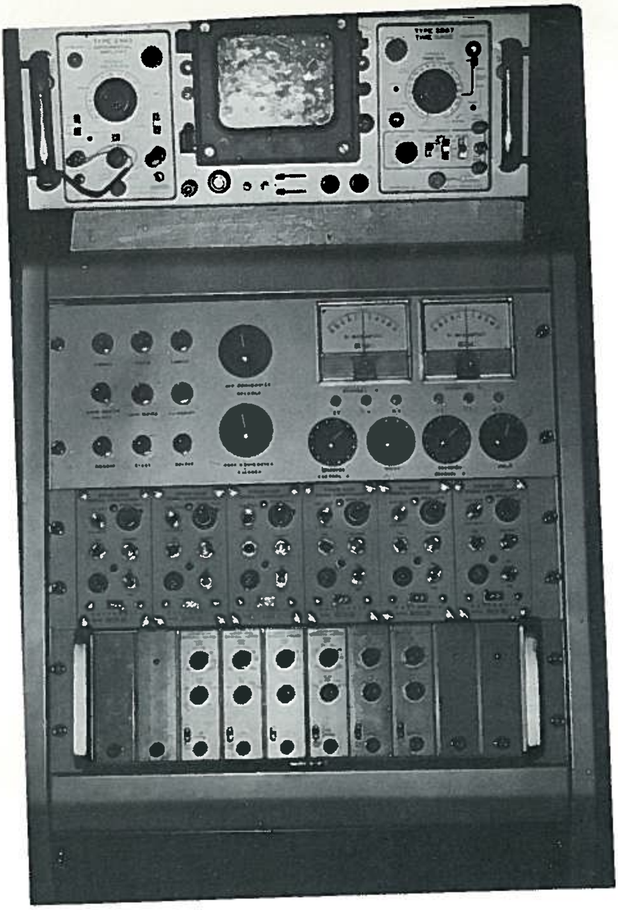

FIGURE 16.—Control panel assembly.

*Automatic Ranging Voltmeters*

Two automatic ranging voltmeters (Channels A&B) were constructed which can operate in either fixed or automatic ranges and which have three full-scale ranges—0.1, 1.0, and 10.0 volts. These meters made it possible to select a channel of interest and visually observe the signal behavior.

*Parallel Signal Monitoring Equipment*

A Tektronix Model 564 memory oscilloscope was attached to Channel A [the left-hand channel], to simultaneously display and record signals. A Sanborn dual channel d.c. strip chart recorder was attached to Channel A and Channel B to simultaneously record a permanent trace of any channel. A Hewlett-Packard Model 419A d.c. null voltmeter was attached to Channel A and used in calibration procedures for higher accuracy work.

*Internal Circuitry*

Each individual panel mounted in the rack is provided with a 32-pin connector. These connectors, as well as one from the experiment in process and one from the primary recording equipment, all connect to a master terminal strip inside the control panel. Thus any individual panel can be powered by disconnecting the 32-pin connector and pulling the module out of the panel. All wiring diagrams and details of the various panels are given in Reference 1 of this section.

## THE COMPUTER PROGRAMS (SOFTWARE)

### Software Development

The development of software for handling multichannel information involves problems in both the collection and processing of data. In most instances the digital computer presents little complexity in the overall problem solution, particularly when dealing with compiler languages such as FORTRAN, MAD, BASIC, etc. In these cases converting the mathematics to a machine algorithm takes little time compared to machine-language programing, and the mathematics can be highly complex. All large machine installations provide this computational capability but are not easily dedicated to the data-gathering aspects of a problem from the economic point of view.

Small machines such as a Linc-8 are easily dedicated to the experimental data-gathering, but usually limited in magnetic core storage within the machine. This means that programs are generally written in machine language rather than compiler language. In turn, it is a more time-consuming process to prepare an individual program. All programs used in this research were written in machine language.

The Linc-8 is equipped with a multiplexed analog/digital converter which provides a convenient method for converting data from analog to digital form convenient for processing by analysis programs. Since these machines have limited magnetic-core storage, full use is made of additional input/output equipment such as the magnetic tape decks. The 10 Hz teletype presented a problem due to its speed. Conversation with the machine was mostly handled via the Tektronix 561 oscilloscope except where a typed copy was absolutely necessary.

### Executive System

The computer came equipped with a standard executive system from which individual programs may be called and executed; all executable programs are stored in its library. Unfortunately, the binary storage area for programs on tape was limited to a small percentage of the total tape length. Since requirements exceeded this limit, it was necessary to devise a means for enlarging the functional capacity of the executive system. This was accomplished by removing from magnetic tape the assembler and manuscript file-storage area present on the standard executive system, thus allowing the binary storage area to encompass the entire tape except for the small amount required for the executive system. By judicious placement of the executive system and the index format of the program library on the tape, compatibility was maintained with manufacturer's supplied programs and the St. Louis University machine-language assembling program—inherent attributes of our Linc-8 computer. A queue routine was added to allow execution of a list of programs rather than single programs. Because of the size of core memory available, the degree of supervision exerted during execution of any individual program is nil. Its inter-active function is to load a program in memory and provide means for return after completion.


FIGURE 17.—Executive system inquiry display.

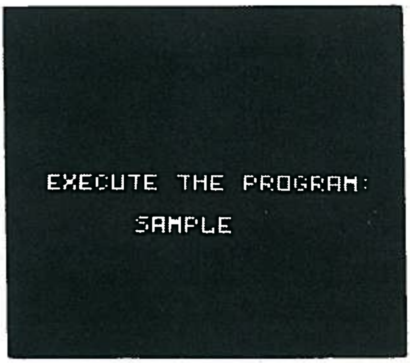


FIGURE 18.—An example of input from teletype.

The first step in executing computer programs related to a given research topic is to load the executive system into memory and selecting the desired program from its library. When the system is fully loaded, the display shown in Figure 17 will appear on the cathode-ray tube over Channel 0; this display merely inquires of the user which program he wishes to execute. As the program name is typed it appears on the oscilloscope as in Figure 18. But if instead of a single program the user calls for display of the index, the oscilloscope will show a list of titles, as in Figure 19, and the user may type the desired program name into this display (Fig. 20). The queue feature can be signalled by typing "QUEUE" or some abbreviation of this term, followed by a list of programs which are to be executed in the order given.

While the executive system is running it renders inoperative all the Linc console switches except "LOAD" and "STOP." If necessary, however, this feature can be overridden at any given point. In addition,

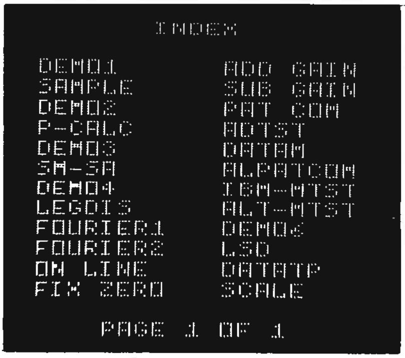


FIGURE 19.—Executive system index display.


FIGURE 20.—Program name with index display showing.

specific allowance is made for hidden programs—those not shown in the index—and for unloadable programs—those the executive system will not load. The first of these two features serves as a protection for novices, and the second offers the advantage of allocating additional tape to any program.

Operational details for this and other computer programs may be found in Appendix 1 of Reference 3.

## Program Library

The library of titles compiled for this pressure study represents programs for collecting and analyzing data recorded from instruments inserted at the interface between a stump and a prosthesis. The programs can be executed by typing the library titles. For example, "P-CALC" designates a three-dimensional display program involving a computational curve-fitting routine. Following are brief descriptions of the programs written or altered for the pressure studies.

### *Program Sample*

This is a sampling program designed to obtain the analog data in digital form by using the analog/digital converter. Its function is to gather the data and write the results on magnetic tape in some predetermined format.

The data tape is always mounted on tape unit No. 1. The entire magnetic tape is used to store digitized experimental data, including the experimenter's comments regarding the testing and loading protection against inadvertent hardware program loads from the tape. The information layouts on tape were chosen to provide ease of programing as well as information retrieval. When the program is loaded, the display shown in Figure 21 will appear. The user then answers the question whether the required data tape is new or existing, and also specifies the


FIGURE 21.—"SAMPLE" program first frame.

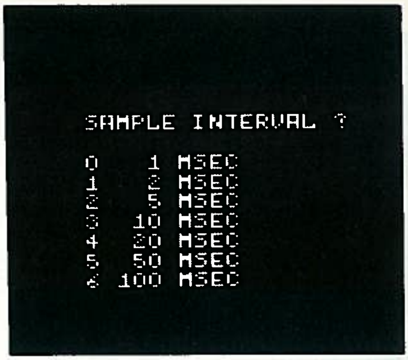


FIGURE 22.—"SAMPLE" program second frame.

sampling interval (Fig. 22). The next frame asks for a four-character alpha-numeric patient identification number (Fig. 23). When typed in, this ID becomes part of the record upon any subsequent use of the data. The next step is to apply the zero-checking routine which was adapted from the program library supplied with the computer (Fig. 24). This allows the user to set "zero" on all instruments in the static condition; it is not intended to be a dynamic digital voltmeter. The patient I.D. is displayed along with the next test number.


FIGURE 23.—Patient I.D.

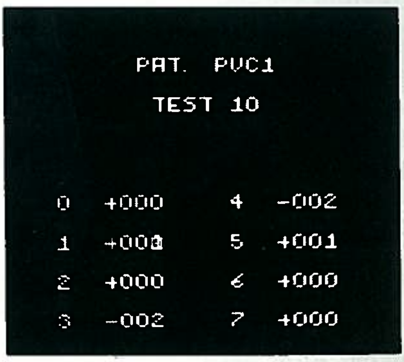


FIGURE 24.—Zero checking routine.

At this point in the operation the machine will no longer respond to the teletype but now senses three external lines which are triggered from the remote control panel. The sampling process begins when the "START" button on the remote control panel is pushed. After 256 points per channel have been sampled the machine will make some preliminary checks on the digitized data just gathered. If neither condition exists, the machine proceeds with the writing of magnetic tape; if either or both exist, it will provide a program interrupt. The interrupt routine will define the type of error and also designate the channel number. A typical interrupt for negative data is shown in Figure 25.


FIGURE 25.—Typical interrupt for Negative Data.

The program maintains a count of the last position in the data field on magnetic tape. It does this by two different methods in order to provide a double check on this information.

If during the sampling process there is a need to discontinue the sampling, the process can be halted by pushing in the "DELETE" button. If the machine is waiting to start sampling and "DELETE" is pushed, the program will delete the data of the last test. "DELETE" may be pushed as many times as desired, thereby deleting data starting with that of the last test and proceeding to the second last test, etc.

If an interrupt occurs during the sampling process the data may be retained by pushing "START" and proceeding when a new test number appears as in Figure 24. Indicator lights on the remote control panel are PAUSE, SAMPLE, TAPE WRITE, and INTERRUPT indicator lights. After the sampling is completed, the SIGNOFF button is pushed, returning the program to the executive system. If SIGNOFF is not used, and this magnetic tape is later used to continue taking data, the program will provide an interrupt indicating improper previous exit.

*Program P-CALC*

"P-CALC" is a three-dimensional display program to display pressure applied to a surface. The program displays two dimensions in space coordinates and one dimension in pressure. It is a computational curve-fitting routine to expand the five pressure channels from discrete points to a spatial curve. The program calculates on data gathered by the program sample described in the above section. It operates with the machine's Tektronix 561 oscilloscope set to Channel 0 and a remote Tektronix 564 oscilloscope set to Channel 1.

The program retrieves five instantaneous pressure values and fits them to a mathematical relationship. The relationship chosen was a polynomial power series. A two-dimensional infinite series expansion in pressure would look as follows:

$$P(X,Y) = A_0 + A_1X + A_2X^2 + A_3X^3 + \ldots B_0 + B_1Y + B_2Y^2 + B_3Y^3 + \ldots$$

For this application the series was truncated and simplified as follows:

$$P(X,Y) = A_1X + A_2X^2 + B_1Y + B_2Y^2 + C$$

where $A_1$, $A_2$, $B_1$, $B_2$, and C are parametric functions of time. This approximation provides a second order polynomial expansion in two spatial coordinates. The selection of this relationship is a matter of choice. It was felt that arguments regarding other possibilities could and should be raised during the experimental portion of the work. At that time, experimental matching of adjacent areas would serve as a mode of evaluation.

During execution of the program, one can specify the test number, interval size, or print-out of the parameters used in the equation solution. The transducer matrix upon which the calculation is executed is a square. The transducers were arranged in a 0.5-in. square with one transducer at the intersection of the diagonals.

The program normalizes this matrix which is inserted at the pressure area and places one transducer output value in each corner of the 564 oscilloscope screen and one transducer output value in the center. These pressures and their locations substituted into the power series equation establish five simultaneous equations with the parametric functions of time $A_1$, $A_2$, $B_1$, $B_2$, and C as unknowns. Simultaneous solution of the set of equations establishes values for the parametric functions. Thereafter, intermediate values of X and Y are fed back into the equations to yield the interpolated values of pressure corresponding to the positions lying between those of the experimental grid. The program then divides the X axis into 32 increments and the Y axis into 21 increments and calculates 672 interpolated values. It also defines, for display purposes, a gray scale from 0 through 7 and assigns each of the 672 points to a gray scale value. The calculated points have a 4 x 6 grid on the scope face and the gray scale range intensifies between 0 and 24 raster points in each grid. Attention was given to the order in which the raster points appeared .so as to assure uniformity and continuity to the light scale representation of pressure changes. Figure 26 shows an example of the resulting pressure display with all eight gray scale pressure levels indicated. The dot densities are proportional to the measured pressure.

*SM-SA*

This program is an attempt to treat skin tissue grossly in the same manner as a conventional engineering material. The intent is not to define tissue tolerance, but pressure tolerance. It is not suggested that

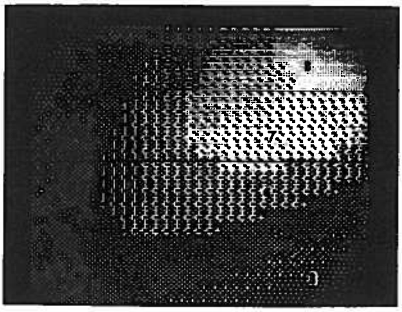

FIGURE 26.—Example display showing all eight gray scale dot densities.

tissue reacts atomically the same as metals, but perhaps that we will be able to present dynamic pressure conditions in a similar manner.

Metals often exhibit a phenomenon called fatigue, which is a result of repetitive loading. Although a metal initially can withstand the dynamic loads to which it is subjected, at a later time the metal fractures for no visually apparent reason. On a microscopic level, there is a basic understanding of the atomic movements occurring that result in fracture. Engineers are able to describe the stress conditions and predict when and if fracture will occur. This is done, basically, by constructing a mean stress-alternating stress diagram. The designer then calculates the expected loading conditions to which the material will be subjected and plots the point on the graph that describes the operating condition. Superimposed on the graph are curves characteristic of the material's properties. A comparison between the operating condition and material characteristics is then made to determine if fracture will occur.

With tissue as the material it would be difficult to construct a fatigue diagram if it exists with material characteristics that would accurately represent skin tissue for different individuals. Instead, this program will calculate the mean and alternating stress values [pressure] which have occurred on an individual, and plot the point. The only intent of the program is to determine whether an operating range exists and if not, to at least characterize the total data for an individual.

The program requires a data tape to be mounted on Unit 1. The software will immediately start searching tape Unit 1, gathering all pressure information from the tape and display as a result a mean stress-alternating stress diagram. The mean stress is defined as the arithmetic average of the minimum and maximum stress occurring on one test for one transducer. The display of the results is shown in Figure 27.

*LEGDIS*

The intent of this program is to reproduce the digitized data taken with program "SAMPLE," in almost an analog form. It is an observation

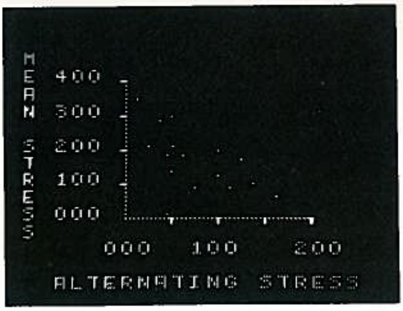


FIGURE 27.—Example display of "SM-SA."

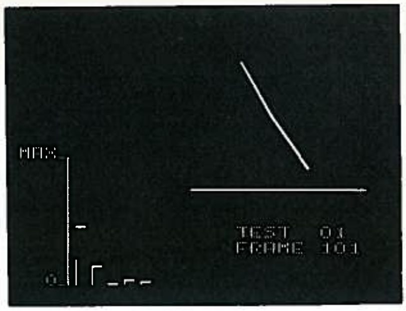


FIGURE 28.—Instantaneous exposure of "LEGDIS" showing leg and prosthesis position, instantaneous pressure, maximum pressures attained thus far, test number, and frame number.

program, performing no calculations on the existing data, but reconstructing the digitized data for concept.

The program constructs a stick figure to represent the patient's leg and draws the hip and knee angle to correspond to the test data. This construction is accomplished by affixing the coordinate system to the vertex of the hip angle. Reconstruction of the angles is displayed in approximately 6-deg. increments. This was necessary as a result of display problems on the digital oscilloscope which displays raster points.

In addition to the stick-figure construction, the program also displays five pressure manometers to represent each pressure transducer. These vertical manometers display a height representative of the pressure magnitude. Attached to each manometer are maximum pointers that indicate the maximum pressure attained during an individual test (Fig. 28).

The program can be controlled to allow specification of any test number, instantaneous frame number, or cycling speed.

*Fourier1*

The purpose of this program is to determine the frequency content of all pressure, hip and knee signals gathered by program "SAMPLE." The equation solved is the Fourier infinite series;

$$f(t) = \frac{a_o}{2} + \sum_{n=1}^{\infty} a_n \cos \frac{2n\pi t}{Y} + b_n \sin \frac{2n\pi t}{Y}$$

where

$$a_n = \frac{2}{2N+1} \sum_{p=1}^{2N} f_p(t) \sin \frac{2\pi pn}{2N+1}$$

$$b_n = \frac{2}{2N+1} \sum_{p=1}^{2N} f_p(t) \sin \frac{2\pi pn}{2N+1}$$

and n=1,2, . . . , N, p=0,1, . . . , 2N and $f_p$ (t) are the values of a given function. This classical equation is solvable by many numerical techniques. One of the more popular solutions uses a recursive technique described by Goertzel (11). The reader is referred to the literature for a complete development of the algorithm. The algorithm requires that one cycle of data be passed to the program for synthesis. The definition of a cycle is defined by the foot-switch information. Figure 29 shows a typical trace of foot-switch information. The foot switch shows a periodicity, one cycle of information lying between the leading edges of two consecutive cycles. This means that the program counts down the zero line and determines when the first switch was closed. It then counts the time from when this switching occurred, while pressure and other parameters are changing, until a zero line is reestablished. When it then finds another switch closure, it stops the interval count. Multiplying the interval count by the interval time establishes the fundamental period or frequency. The program was written to perform the analysis on any of the sampling rates in the program "SAMPLE."

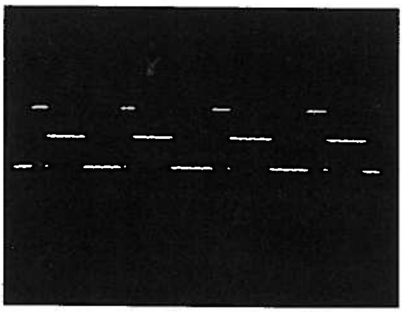

FIGURE 29.—Foot-switch trace obtained from program "DATAM."

The program output is completely handled by the teletype. It titles the paper with block number and period size in data points to the base eight. Then it lists five columns of numbers. The left column is a counter "P." The second column is the frequency (Hertz); the third is the "A" coefficient. The fourth column is the "B" coefficient and the fifth column is the normalized amplitude which is defined as follows:

$$\text{Normalized Amplitude}=\left[\frac{A(K)^2+B(K)^2}{A(F)^2+B(F)^2}\right]$$

where K equals the instantaneous value and F equals the fundamental value.

Although for this research no problems were anticipated regarding frequency response of the hardware, future research may benefit by requiring less expensive signal processing and recording equipment. This program was written to provide basic signal definition for this and other general purposes.

An example output is shown in Figure 30 for a 20,000 microsecond sampling interval. Note that the program determines the fundamental frequency, and in the right margin marks it with an "F." It computes this independent of position. It should always be in the first position as shown.

BLOCK NO. 020 FOURIER1 PERIOD 103

| P | FREQUENCY.C/S. | A.P.COS | B.P.SIN | N=NORM. AMPL. | |
|---|---|---|---|---|---|
| 000 | +0.000000E+000 | +9.773132E+001 | | | |
| 001 | +7.462691E-001 | +7.005947E+000 | +3.925976E+001 | +1.000000E+000 | F |
| 002 | +1.492537E+000 | +2.321539E+001 | +2.056045E+001 | +7.776110E-001 | |
| 003 | +2.238805E+000 | +7.030235E-001 | +1.422734E+001 | +3.571895E-001 | |
| 004 | +2.985075E+000 | +6.398669E-003 | +1.554550E+001 | +3.898077E-001 | |
| 005 | +3.731343E+000 | +2.062622E+000 | -9.126983E-001 | +5.655806E-002 | |
| 006 | +4.477611E+000 | +2.512415E+000 | -6.914996E-001 | +6.534212E-002 | |
| 007 | +5.223880E+000 | +1.171954E+001 | +3.447669E+000 | +3.063228E-001 | |
| 008 | +5.970149E+000 | +6.053598E+000 | +3.971033E+000 | +1.815406E-001 | |
| 009 | +6.716417E+000 | -1.841258E-002 | +6.834828E+000 | +1.713856E-001 | |
| 010 | +7.462686E+000 | +1.154971E+000 | -1.847719E+000 | +5.463887E-002 | |
| 011 | +8.208953E+000 | +1.450445E+000 | -4.813061E+000 | +1.260497E-001 | |
| 012 | +8.955224E+000 | +7.778982E+000 | -4.150466E-001 | +1.953373E-001 | |
| 013 | +9.701492E+000 | +6.013542E+000 | +9.418975E-001 | +1.526295E-001 | |
| 014 | +1.044776E+001 | -6.873037E-001 | +3.161689E+000 | +8.113181E-002 | |
| 015 | +1.119402E+001 | -2.420089E-001 | -1.716941E+000 | +4.347829E-002 | |
| 016 | +1.194029E+001 | +7.170506E-001 | -6.283661E+000 | +1.585869E-001 | |
| 017 | +1.268656E+001 | +4.478830E+000 | -2.120114E+000 | +1.242548E-001 | |
| 018 | +1.343283E+001 | +4.665005E+000 | -3.075885E-001 | +1.172301E-001 | |
| 019 | +1.417910E+001 | -1.379102E+000 | +9.550754E-001 | +4.206435E-002 | |
| 020 | +1.492537E+001 | -1.654171E+000 | -1.483026E+000 | +5.570799E-002 | |
| 021 | +1.567163E+001 | -3.001363E-001 | -5.784392E+000 | +1.452401E-001 | |
| 022 | +1.641790E+001 | +1.513542E+000 | -2.713197E+000 | +7.790399E-002 | |
| 023 | +1.716417E+001 | +2.802378E+000 | -4.352711E-001 | +7.111292E-002 | |
| 024 | +1.791044E+001 | -1.880110E+000 | -2.564454E-001 | +4.758074E-002 | |
| 025 | +1.865671E+001 | -2.615665E+000 | -5.936437E-001 | +6.725647E-002 | |
| 026 | +1.940298E+001 | -1.053929E+000 | -4.009460E+000 | +1.039535E-001 | |
| 027 | +2.014925E+001 | -7.929094E-001 | -2.299102E+000 | +6.098276E-002 | |
| 028 | +2.089552E+001 | +9.443503E-001 | -1.942458E-001 | +2.417555E-002 | |
| 029 | +2.164179E+001 | -1.515900E+000 | -6.579629E-001 | +4.143770E-002 | |
| 030 | +2.238805E+001 | -2.966858E+000 | +4.402773E-001 | +7.520944E-002 | |
| 031 | +2.313432E+001 | -1.550366E+000 | -1.446582E+000 | +5.317039E-002 | |
| 032 | +2.388059E+001 | -2.331101E+000 | -1.586531E+000 | +7.070650E-002 | |
| 033 | +2.462686E+001 | -6.739224E-001 | +2.730496E-001 | +1.823311E-002 | |

FIGURE 30.—Typical output from "FOURIER1," sample interval equals 20,000 microseconds.

### *Program Fix Zero*

In some of the early investigations, it was found that the temperature sensitivity of the transducer had an appreciable effect on zero-offset. Two basic alternatives exist to correct this condition. The first and most straight-forward was to assure that the original data were taken only after the transducer had stabilized to a new zero. In this case, the transducers were zeroed immediately before taking data. The second alternative was to have a program correct for the zero-offset condition after data were taken, by forcing the minimum value pressure to zero and translating the entire curve accordingly. After loading, the program scans the data tape by reading in each individual channel of pressure data, finds the minimum value, adds or substracts it to all data points, and rewrites the magnetic tape.

*Program Datam*

This program was written to retrieve one channel of data from a single test and display it in a convenient format. After specifying a particular piece of data, the program finds the information from a data tape mounted on Unit 1. A trace from a pressure transducer is shown in Figure 31 with coordinate system.

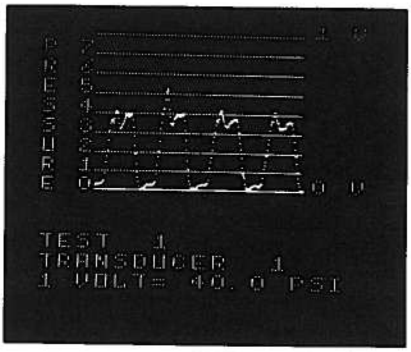


FIGURE 31.—Typical pressure data recalled by program "DATAM."

The display can be shown as in the figure or without the vertical graduations and scale, test number, transducer number and scale factor. The vertical numbering of the pressure ordinate on the left side refers to the gray scale values represented in the program "P-CALC." The ordinate on the right side refers to voltage level, from 0 to 1 volt. The test number and transducer number are automatically calculated and displayed by the program. The test number refers to the sequential test referenced and the transducer number to the pressure transducer represented. Since the full scale pressure value is dependent upon the hardware during acquisition, this number is typed in during the display.

*LSD*

"LSD" is a two-dimensional display program utilizing the Tektronix 564 memory oscilloscope. The program displays a set of pressure values in one spatial coordinate from a rectilinear array of pressure transducers. The curve-fitting routine expands five pressure points from discrete values to a complex curve. The program computes on data gathered by the sample program described in the "Program Sample" section. The program retrieves five instantaneous pressure values and fits them to a mathematic relationship. The relationship chosen was a truncated polynomial power series:

$$P(X) = A_0 + A_1X + A_2 + X^2 + A_3X^3 + A_4X^4$$

where $A_0$, $A_1$, $A_2$, $A_3$, and $A_4$ are parametric functions of time.

The program solves the equation for the $A_n$ parameters from the five discrete equally spaced transducers. It then divides the X-axis into 100 equal increments and interpolates the value at each point and displays the resulting curve.

At any time the user can specify test number, frame number, or stop the display temporarily. Its control is very similar to "P-CALC." Program interrupts, indicating bad results or poorly formatted data, are the same as in "P-CALC."

Related programs were developed to aid in formulating the experimental protocol, and adding versatility to the displays. These are discussed in detail in Reference 1.

## EXPERIMENTAL WORK

### Application of the Instrumentation

The application of the pressure transducers to the stump was done after palpating the anatomical reference point and drawing the zones on the limb. In general, it was found that after insertion and removal of the prosthesis, the transducers did not move perceptibly on the skin. In rare instances, it was necessary to reapply the instruments, taking the data a second time.

When the subject had a thigh corset attached to the prosthesis, it was necessary to cut a hole in the stump sock just above the brim of the prosthesis and feed the lead wires through this hole. It was done in this manner to avoid the problem of running the lead wires all the way up to the hip in order to mate with the harness connector.

The major pressure transducer application problem was encountered in the application of the transducer to a stump with redundant tissue. On such a stump, normally firm tissue degenerates to excess fat tissue which provides a considerable amount of relative movement between the tibia and the skin tissue. During the application of the array on this type of stump the transducers tend to pull loose from the taped position during insertion as a result of inelastic ribbon-cable. This condition was encountered on two subjects and testing had to be halted.

The hip and knee goniometers were applied in a straightforward manner. The greatest concern was the alignment of goniometer axes with anatomical axes. With reference to anatomical landmarks the axis of rotation of the knee is located approximately ¾ in. above the medial tibial plateau edge on an extension of the posterior edge of the tibia

(12). The hip axis was found anterior to the greater trochanter (13). In both the above cases, having the subject flex the hip and knee joint and observing the alignment of goniometer axis relative to the anatomy, as well as checking the straps for tightening or loosening during flexion, revealed deviations and led to more precise axis alignment.

The three foot switches were attached to the heel and sole of the shoe with skin tape. The heel and toe switches were taped at the extreme ends of the shoe and the intermediate switch located approximately at the ball of the foot. Since all three of these switches provided only relative gait signals, positioning did not need to be exact.

**Data Collection**

In general, experimental work took between 2 and 3 hours for an individual patient. It was found that the method of application of the transducers to the stump consumed most of the time during data acquisition. When the method of encapsulating the transducers as a fixed array was developed, it reduced the application time sufficiently and allowed gathering of three to four times the amount of data previously taken in one experimental session. During the early work at least eight zones were measured so that an integrated pressure area could be assembled. The majority of data gathered was from the kick-point zones and on one subject a complete mapping of the patellar-tendon region was done. For the mapping work six subjects formed the basic final data, and six other subjects were used to establish experimental techniques. On a later study, pointed toward evaluation of liner materials (14), 26 subjects were measured at four critical stump areas.

**Pressure Mapping on an Area**

With the aid of program "P-CALC" and the program "LEGDIS," a reconstruction of a ½ in. by ½ in. area can be accomplished and correlated with gait information. This type of computer-generated information is shown in Figure 32 and indicates the presence and form of the pressure profile occurring during a fraction of the walking cycle. The pressure display information is viewed from left to right, top to bottom, with the reconstruction of the stick figure and pressure manometers directly beneath each frame. For purposes of comparison, each gray scale represents a range of 5 p.s.i.

The first frame indicates only a small pressure ridge [5-10 p.s.i.g.] extending from transducer P4 to P3, while the second frame indicates that a uniform pressure distribution has built up. The individual frames of the display indicate that a pressure wave entered from the bottom of the test area and traveled approximately halfway across the test area and then altered directions and moved off to the right-hand side of the display until it eventually disappeared.

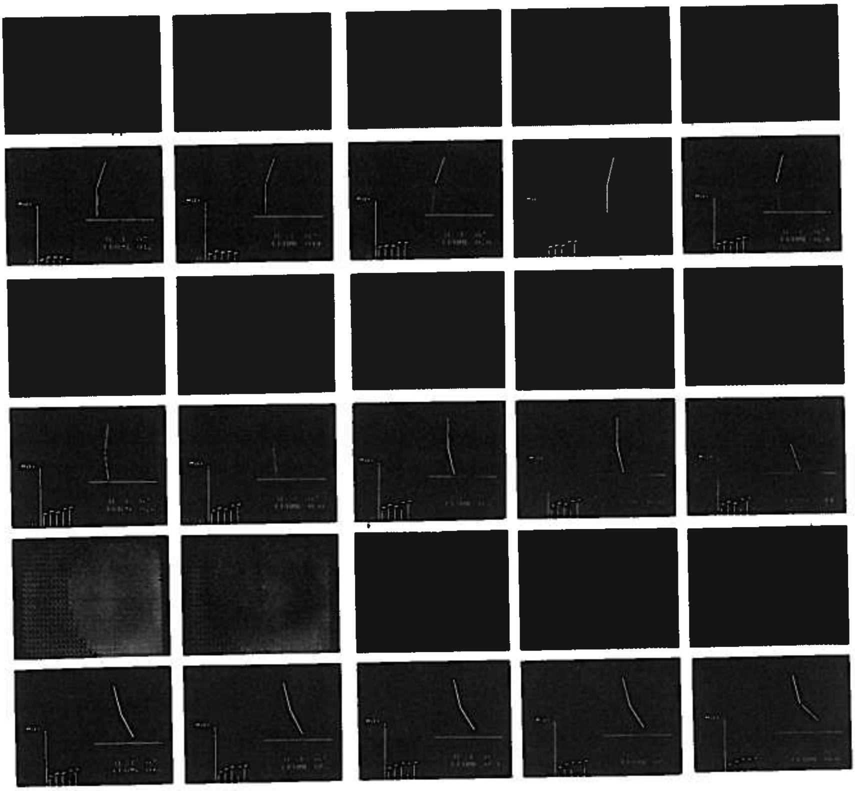

FIGURE 32.—Composite showing the correlated output from program "P-CALC" and program "LEGDIS." Gray scale shows 5 p.s.i.g. per level, 40 p.s.i.g. full scale (Patient No. 10).

This test was run on kick-point Zone D on a left below-knee amputee and shows that the pressure started on the distal end of the stump building toward the kick-point and relieved by moving toward the lateral side of the socket. The highest pressure attained was 10-15 p.s.i.g.

In viewing only the stick-figure construction, the fixed amount of flexion built in the prosthesis appears quite vividly.

When data are acquired from adjacent areas on the anatomy, the results of individual transducer arrays can be placed side-by-side to reconstruct a larger area. In order to demonstrate this principle, a demonstration version of the program "P-CALC" was used to reconstruct a hypothetical pressure region. In Figure 33a the pressure specifications and resulting pressure are shown. In the upper portion, octal pressure specifications (400 octal=40 p.s.i.) were entered for each individual area. In the upper left corner, the array consisted of five pressure values, P1 having a value of 100, P2 a value of 200, P3 a value of 250, P4 a value of 310, and P5 a value of 340. The resulting pressure display is shown in

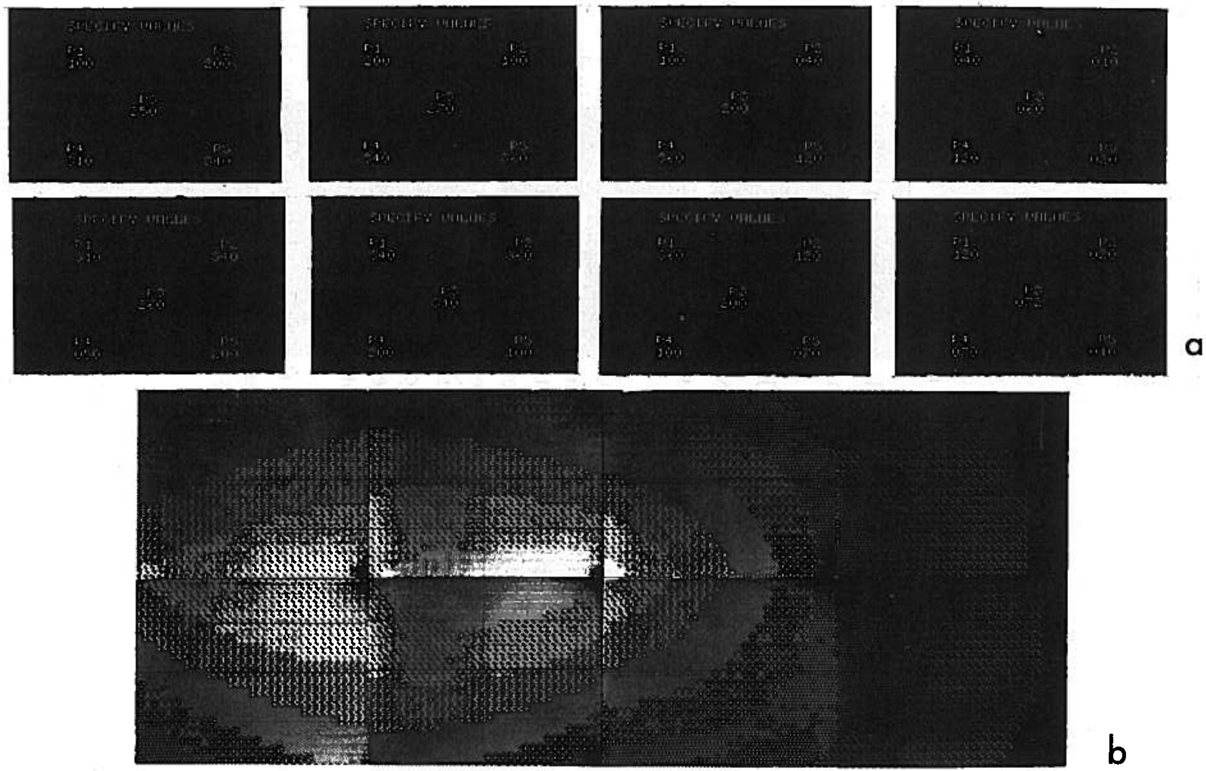

FIGURE 33.—Hypothetical reconstruction of an area of pressure: (a) Octal values chosen for the individual arrays, (b) resulting region mapping.

the upper left-hand corner of Figure 33b. When eight adjacent areas were calculated and placed side by side, the area reconstruction shown in Figure 33b was produced. The results show an adequate representation of the hypothetical profile. Note that concurrent points show identical pressure readings.

*Reconstruction of Pressure Profiles Using Patient Data*

In using actual patient data several problems were encountered, all relative to mismatching of instantaneous pressure values at adjacent sites of the transducer array during the mapping process. Specifically:

1. Successive pressure zones were recorded during different steps (separated by as long as 15 minutes). Accordingly all the difficulties of matching non-identical studies were encountered. That is, data taken each 20 milliseconds on one stride do not match with consecutive 20-millisecond intervals on the next stride.
2. The exact location of the stump in the socket varies slightly each time the limb is put on.
3. Transducer arrays move slightly in use.
4. Individual transducer zero-pressure values drift slightly.
5. Individual transducer calibrations are not exact.
6. Other factors, yet unknown.

Typical difficulties are shown, using the "DATAM" display, in Figure 34, where each group of four displays shows data from a single point on the stump. Ideally the time history, even taken on separate steps, would be identical. The peaks however vary by as much as a factor of three. The relative importance of the six "mismatching" problems listed above have not been satisfactorily delineated at the time of this writing. The transducer calibration and zero-drift problems are probably least important. Since the transducers are significantly sensitive to bending, and because the diaphragm does not receive a true pressure but rather discrete forces in contact with the irregular anatomy, these may be primary factors and would fall into the "yet unknown" listing above.

These and other aspects of the matching problem are discussed in considerable detail in Chapter V of Reference 1.

## Linear Pressure Mapping

This program computes on a linear array of transducers spaced one-half inch apart. Figure 35a shows the pressure traces obtained from program "DATAM" for a linear array of transducers. For the linear array, data were acquired from the anterior crest of the tibia. The array ran from a position ½ in. on the +X axis up and parallel to the +Y axis. Transducer P5 was located at the X=½, Y=0 position. Figure 35b

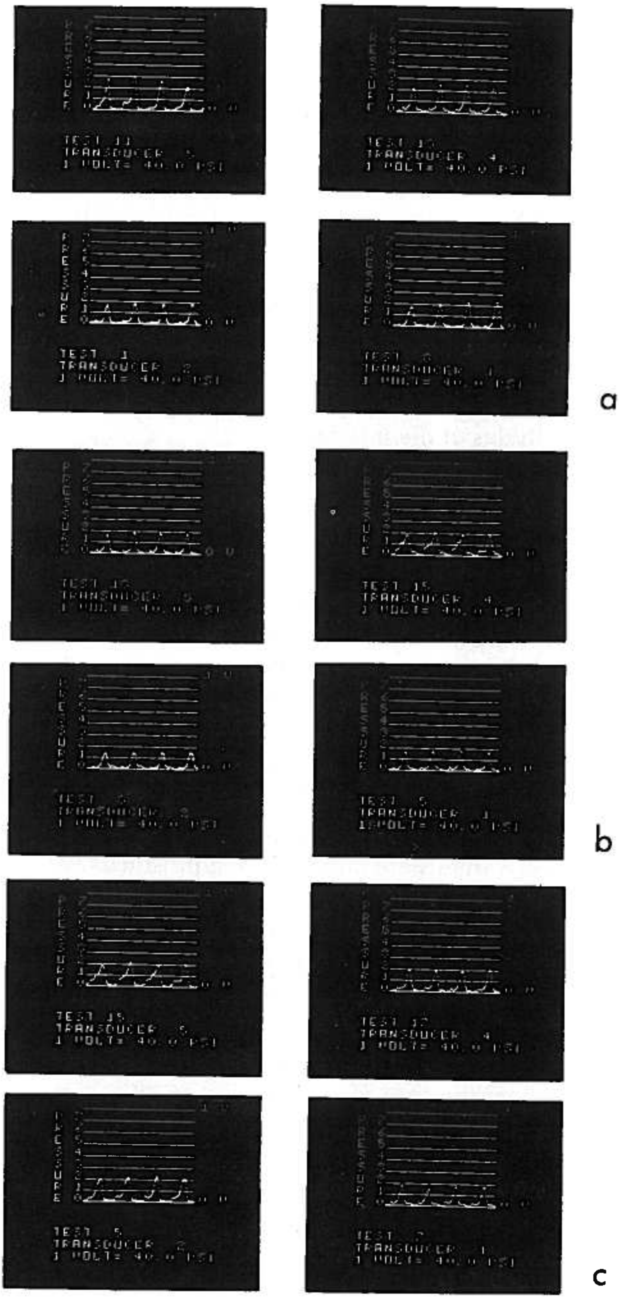


FIGURE 34.—Pressure curves at the major intersection points (original data) reproduced by program "DATAM" (Patient No. 10).

shows a parametric representation in time of the pressure curves. Nine curves are displayed on each photograph and the photographs continue from left to right, top to bottom, presenting the pressure wave measured by transducers P1 through P5 as a continuous function of time from the first photograph to the last. In this instance, every other data point was used to construct the graphs. That is to say, 126 curves are shown in the 14 pictures.

It might be noted that the maximum pressure values of 15 lb. p.s.i. occur ½ in. laterally and 2 in. proximally from the kick point for this setting of the linear array of gages. Since this region has not yet been scanned, no conclusions can be drawn that this represents the optimal pressure value.

## Pressure Magnitudes at the Interface

In order to view the aggregate of data and disclose the range of pressures at the kick-point and patellar regions, the results were studied using program "SM-SA" (Fig. 36). It might be anticipated that the pressure would have a nonzero value during swing phase in some regions. This did not occur. The tissue was subjected to zero or nearly zero pressure while the subject was seated, and the same was true during most of the swing phase. Since the pressure at a point is represented by a curve going from zero to some maximum value and returning, the data plotted on these graphs exhibit linear characteristics. In a plot of this type the maximum stress of pressure is the sum of the abscissa value plus the ordinate value.

In Figure 36a, b, c, d, the data were acquired from the kick-point region. The higher values were obtained on a prosthesis with a cuff suspension for a diabetic subject. This means that the subject had much less sensitivity at the distal end of the stump than a subject traumatically amputated. The lower value pressures shown in the (c) and (d) portions of this figure were obtained from subjects having very good skin sensitivity.

Figure 36 shows results of data acquired from the patellar region. These results show pressure values ranging to 40 p.s.i.g.

Although it is tempting to believe that the skin tissue in a below-knee prosthesis is subjected to relatively uniform pressures, it is obvious from these that a wide variety of pressures occurs within a patellar-tendon-bearing prosthesis and that relatively sharp pressure gradients do occur. It is also indicated that the highest pressure is not always in the patellar region. Other areas are sometimes subjected to pressure magnitudes equal to or greater than these.

## Pressure Signal Spectrum (0–25 Hz)

An investigation of the signal frequency content was undertaken in

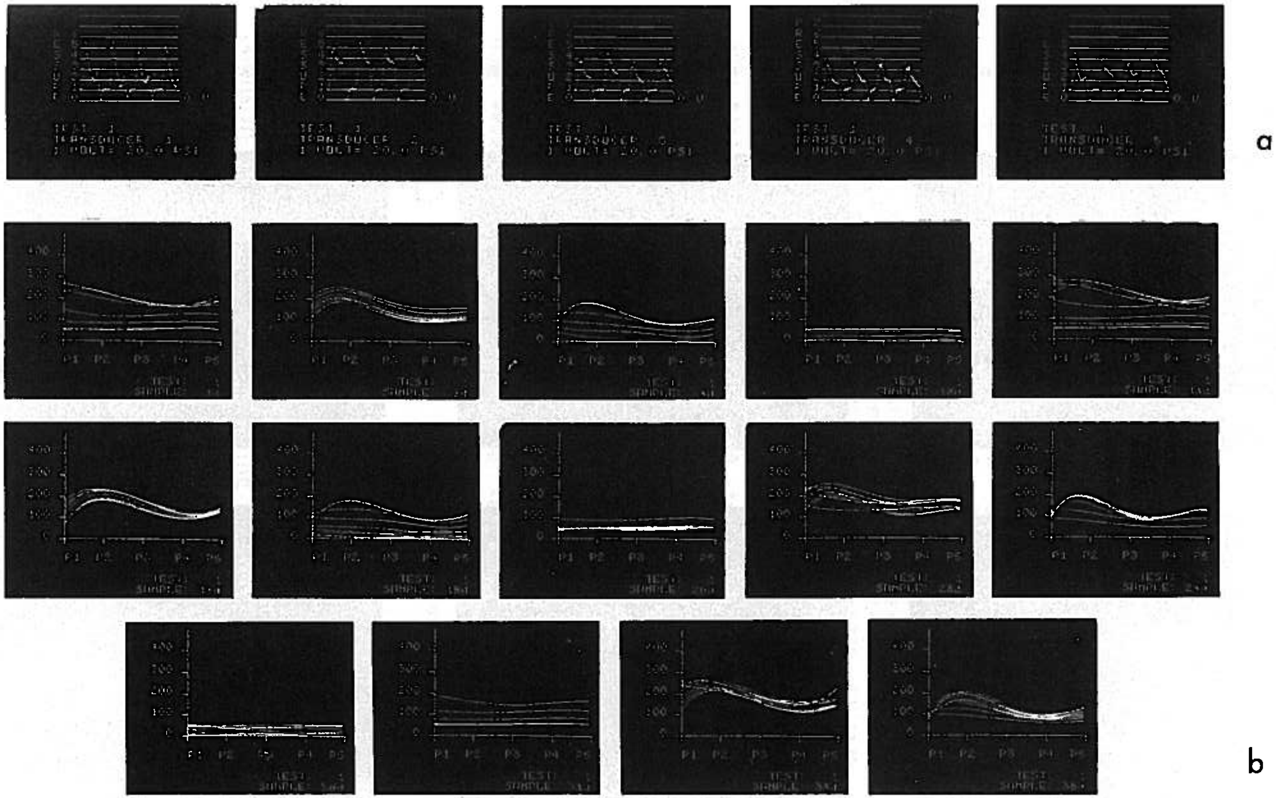


FIGURE 35.—(a) "Rezeroed" pressure curves from the linear array, (b) parametric representation of pressure distribution calculated by program "LSD," 20 p.s.i.g. full scale.

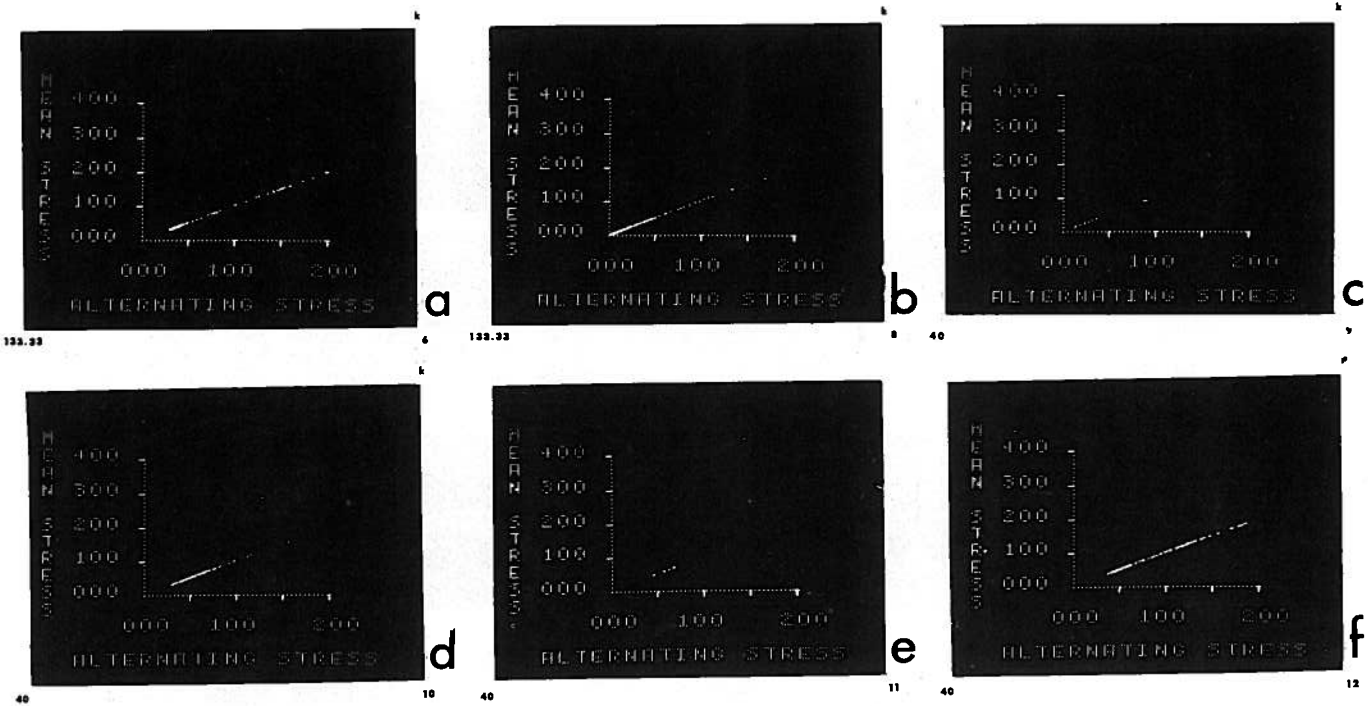


FIGURE 36.—Mean stress-alternating stress representation of all the data acquired. Full scale values: abscissa 20, ordinate 40.

order to better understand the dynamics to which the tissue was being subjected. In this portion of the work, a single cycle of the pressure curve was subjected to a discrete Fourier analysis. A typical print-out of the results of this computation is shown in Figure 37.

BLOCK NO. 010 FOURIER1 PERIOD 101

| P | FREQUENCY.C/S. | A.P.COS | B.P.SIN | N=NORM. AMPL. |
|---|---|---|---|---|
| 000 | +0.000000E+000 | +8.329229E+001 | | |
| 001 | +7.692313E-001 | +9.091224E+000 | +4.090770E+001 | +1.000000E+000 F |
| 002 | +1.538461E+000 | +1.585434E+001 | +8.100387E+000 | +4.248546E-001 |
| 003 | +2.307691E+000 | +1.506445E+000 | +1.657591E+001 | +3.971828E-001 |
| 004 | +3.076922E+000 | +7.185354E+000 | +6.757405E+000 | +2.353774E-001 |
| 005 | +3.846154E+000 | -2.171210E+000 | +4.400255E+000 | +1.170907E-001 |
| 006 | +4.615383E+000 | +5.447136E+000 | +4.283753E-001 | +1.303867E-001 |
| 007 | +5.384615E+000 | +2.137228E+000 | -3.674140E+000 | +1.014308E-001 |
| 008 | +6.153844E+000 | +8.861164E+000 | -1.131461E+000 | +2.131715E-001 |
| 009 | +6.923077E+000 | +7.495172E+000 | -3.358637E+000 | +1.959944E-001 |
| 010 | +7.692307E+000 | +8.971680E+000 | +2.509580E+000 | +2.223100E-001 |
| 011 | +8.461536E+000 | +7.658037E+000 | -3.277392E-001 | +1.829117E-001 |
| 012 | +9.230766E+000 | +5.145286E+000 | +3.458269E+000 | +1.479388E-001 |
| 013 | +1.000000E+001 | +5.138456E+000 | +2.582305E-001 | +1.227741E-001 |
| 014 | +1.076923E+001 | +2.201272E+000 | +1.754299E+000 | +6.717017E-002 |
| 015 | +1.153846E+001 | +4.364347E+000 | +9.987283E-002 | +1.041740E-001 |
| 016 | +1.230768E+001 | +1.318750E+000 | +7.880244E-001 | +3.665982E-002 |
| 017 | +1.307691E+001 | +3.022965E+000 | +1.634795E+000 | +8.201021E-002 |
| 018 | +1.384615E+001 | -7.210539E-001 | +1.136145E+000 | +3.211111E-002 |
| 019 | +1.461538E+001 | -6.619972E-001 | +2.158286E+000 | +5.387164E-002 |
| 020 | +1.538461E+001 | -3.571692E+000 | -6.853668E-001 | +8.678664E-002 |
| 021 | +1.615384E+001 | -4.048837E+000 | -2.807292E-001 | +9.684982E-002 |
| 022 | +1.692307E+001 | -4.080831E+000 | -4.101646E+000 | +1.380695E-001 |
| 023 | +1.769230E+001 | -3.868089E+000 | -3.238664E+000 | +1.203869E-001 |
| 024 | +1.846153E+001 | -2.075191E+000 | -5.233238E+000 | +1.343413E-001 |
| 025 | +1.923076E+001 | -2.726121E+000 | -3.736252E+000 | +1.103685E-001 |
| 026 | +2.000000E+001 | -7.069002E-001 | -4.411924E+000 | +1.066250E-001 |
| 027 | +2.076922E+001 | -2.462131E+000 | -3.786575E+000 | +1.077815E-001 |
| 028 | +2.153846E+001 | -4.837142E-001 | -3.796794E+000 | +9.133561E-002 |
| 029 | +2.230768E+001 | -1.252118E+000 | -4.501240E+000 | +1.114918E-001 |
| 030 | +2.307691E+001 | +1.088577E+000 | -2.906575E+000 | +7.406479E-002 |
| 031 | +2.384615E+001 | +1.282542E+000 | -3.457605E+000 | +8.800264E-002 |
| 032 | +2.461537E+001 | +2.422847E+000 | -8.181379E-002 | +5.784960E-002 |

FIGURE 37.—Representative Fourier analysis of pressure data obtained from "FOURIER1."

Referring to this figure, the column on the extreme left lists the harmonic number starting with the d.c. component. The number of coefficients which can be recovered is a function of the number of data points in one cycle. For the sampling frequency chosen, the program averaged approximately 30 Fourier coefficients.

The data curve and results are illustrated in Figure 38 which shows the data curve and Figure 39 which shows a graph of the amplitude spectrum. In the latter graph, a large decay in the spectrum occurs around the 5-to-6-cycle level, but the higher harmonics do not go to zero.

One of the initial requirements for performing the frequency analysis is that the wave form examined be periodic. This requires that the repeatability of the signal be complete and that the value of the signal

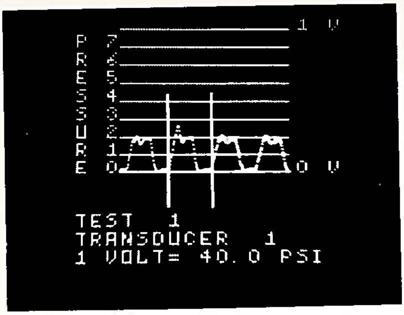


FIGURE 38.—Pressure curve from which Fourier analysis was taken.

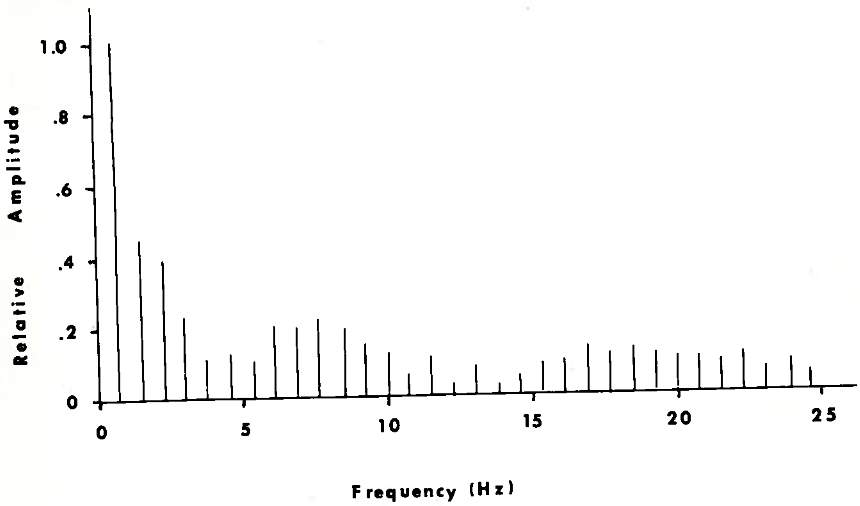


FIGURE 39.—Amplitude spectrum of results obtained from Figure 37.

and its derivatives be in agreement at the interval extremities. The application of these criteria to these experimental data, the interval for which was defined by gait dynamics, would make the calculation impossible. When discontinuities in the signal and its derivatives occur at the interval extremities, higher order harmonics are introduced from the mathematics in its attempt to curve-fit the data, forcing the experimenter to correct for this in either the preparation or interpretation of the data.

A thorough study would include higher sampling rates and more samples per interval. It would also be assisted by a highly repeatable signal which may or may not be experimentally possible.

## Foot-Switch Results

A study was undertaken to examine the pattern that the foot-switches produced during the experimentation period. The foot-switch patterns were compared within an individual test, which constituted approximately four cycles, as well as between tests. Comparison of foot-switch traces within an individual test should evaluate the repeatability of foot contact with the floor during approximately 5 seconds of gait. The comparison of foot-switch traces between tests should evaluate foot contact with the floor after reapplication of the prosthesis.

It has been shown that the pressure traces at a point are repeatable within a test but not reproducible from one test to the next. It can also be stated that the foot-switch traces exhibit the same characteristics. Examinations of printed listings of the data showed that in some instances the subject did not close the foot-switches in the same manner more than half the time. In some instances it was found that the subject did repeat a foot-switch closure pattern a substantial part of the time. Primarily the difference was found to exist at the intermediate and toe foot-switches. Sometimes the subject would conclude a step with the intermediate foot-switch closed and sometimes with only the toe foot-switch closed.

At heel contact, distal pressure is generated and the resulting pressure wave moves up and around the kick-point area. Therefore, transducer positioning must be specified before peak values of pressure at a point can be correlated with foot-switch closure.

In general, the foot-switch pattern consisted of two or three levels which resulted from individual closures of the heel, intermediate, and toe switches. Simultaneous closure of two foot-switches was rare.

The original intent of the foot-switches was to correlate pressure and time curves. Since the general form of the pressure curves exhibit fourth or fifth order power series behavior, a more sophisticated foot-switch timing device is needed.

Alterations in the mechanical construction of the foot-switches as well as electrical signal treatment of their output would improve them. They should be run through a summing transistor or an operational amplifier rather than the resistive network employed so that better voltage increments can be chosen.

In fact, placing one foot-switch on the opposite limb to provide a gaiting signal during swing phase of the leg being tested would facilitate the Fourier analysis. In a large percentage of cases the pressure generated during swing phase is very small and discontinuities in the pressure signal at the extremities of the cycle interval would be minimized. The Fourier analysis would improve by eliminating spurious frequency content.

## Summary

The University of Michigan pressure interface equipment has been developed as a research tool for studies on tissue-adaptive device inter-

faces. This project was conceived as an essential step in the basic understanding of below-knee prosthetics. The hardware was designed to obtain pressure information to two distinct groups of staff members:

1. The physicians who prescribe prostheses and the prosthetists who fabricate them.
2. The engineers who approach the problem from an analytic standpoint and desire quantitative information.

During research, two purposes were proposed and accomplished:

1. A hardware-software system was designed and developed as a research device for studying the basic interface.
2. Preliminary research was conducted with clinical subjects and information obtained on the below-knee prosthesis.

The University of Michigan interface pressure research equipment has been designed around three subsystems:

1. A miniature pressure transducer which was developed in cooperation with the Kulite Semiconductor Products, Inc. It is durable enough for insertion at the prosthesis-limb interface and sensitive enough to obviate expensive electronics.
2. A commercially available signal amplification and data recording system. The introduction of the digital computer into the field of physical medicine and rehabilitation is not limited to this individual study. It represents a new dimension to the research activities within this area and offers a potential for daily clinical activity.
3. The specific software necessary to gather, store, and display meaningful results. This part of the research represents the most flexible component and is limited only by the ingenuity of the researcher.

It has been demonstrated that analog-type displays of digitized computer data can be reconstructed to appear in more meaningful representations than conventional strip chart recordings provide. These graphic representations of pertinent experimental data provide an effective means of communication between the engineer and the medical staff.

It has also been demonstrated that a graphic representation of pressure in an area can be reconstructed to provide a conceptual as well as analytical representation of pressure profile. This area reconstruction has a gray-scale representation adequate for good recognition. Furthermore, it has been shown that these individual areas can be placed side-by-side to reconstruct larger regions of pressure.

The results of the experimental work in the reconstruction of larger pressure regions raise questions about a reproducibility of pressure signals. In spite of the magnitude of the differences in pressure traces, conceptual results were shown. Non-reproducibility is probably the result of four major factors:

1. Repetitive application of the prosthesis, resulting in different alignments of the prosthesis to the bone-tissue composite, or juxtaposition of the soft tissue in relation to the prosthesis shell.
2. The type of suspension system used, which may or may not be controlled by the patient himself. Although the patient apparently has little effect on pressure distribution with cuff-suspension adjustment, he may have significant influence on pressure by the manner in which he puts on a thigh corset.
3. Stump-sock positioning and composition can change with application or time.
4. Individual variations in gait.

It has also been shown that the computer provides indispensable aid in its ability to scale data. This removes a heavy burden from the hardware specifications and experimental procedure common to straight analog recordings. That mapping and curve-fitting of pressure traces are feasible means for examining data was also demonstrated.

Pressure magnitudes are probably not sufficient to categorize pressure interface measurements. The fact that absolute numbers do not show a coherence between patients indicates that the individual's pressure tolerance varies significantly.

The frequency investigation indicates that the tissue is not subjected to low frequency pressure components only, but that high frequency content is also present in the average below-knee prosthesis.

## LINER STUDY

Reference (1) covers a study to determine whether different prosthesis liner materials contribute significantly to different peak pressures during normal walking for a person wearing a PTB prosthesis. Differences were observed and are presented in Figure 40. The study concerned the socket using no liner (hard); the conventional sponge material (Kemblo), and a new silicone gel liner being fabricated and tested at the University of Michigan Medical Center (Gel). The specific areas tested were the two condylar flairs (MTC, LTC), the patellar-tendon region (PT), and the anterior distal region commonly referred to as kick-point (KP). Pressure values shown are the range (lines) of peak values during each step and the average (bars) of peak values.

## HAND-HELD PRESSURE DEVICE

In order to make interface pressure measurements readily available to the prosthetist or clinician, a completely portable device has been designed and built. The unit shown in Figure 41 contains power and

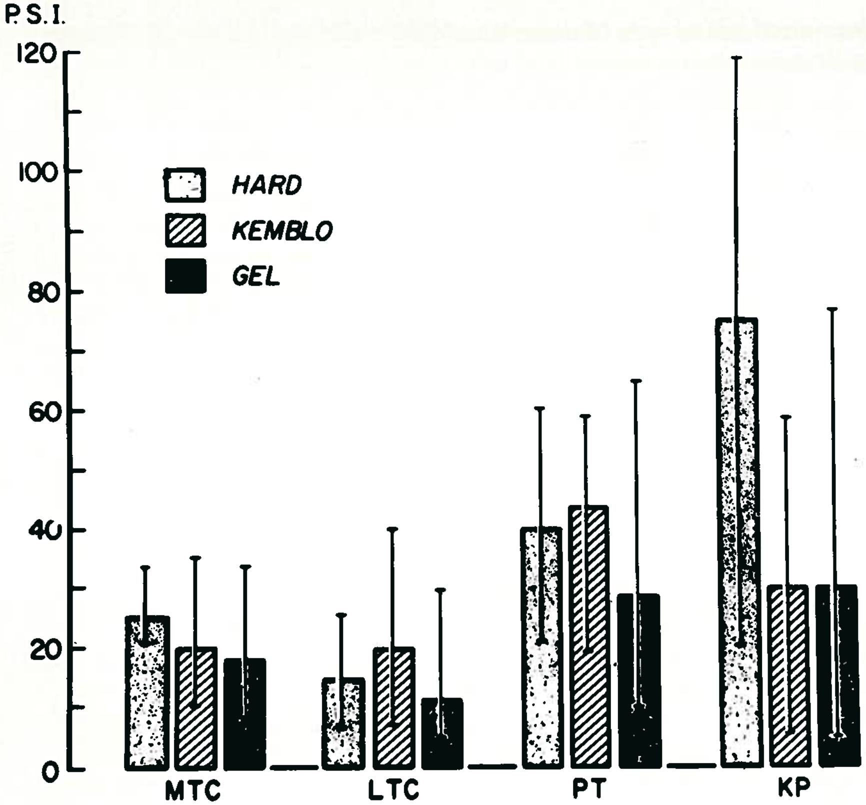


FIGURE 40.—Liner comparison for the average of peak pressures observed at four areas during walking.

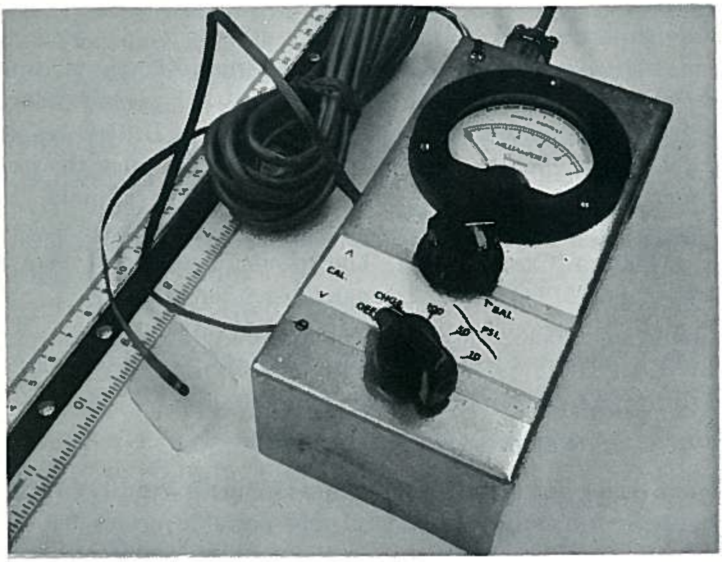

FIGURE 41.—Hand-held interface pressure instrument.

indicating circuitry for a single Kulite transducer. Full-scale pressure readings of 10, 50, or 100 p.s.i. can be selected. Provision is made for an independent standardizing signal of 10 p.s.i., and zero correction is readily made at the front panel. Through an external socket the output (0-1 v. F.S.; into 500 ohms or greater) can be connected to a recording or display device or a computer. The self-contained cells provide about 15 hours of continuous operation when fully charged. At current prices the cost of the device is broken down into these estimates of components:

| | |
|---|---|
| LPS–200 transducer | $325.00 |
| Hardware | $50.00 |
| Assembly | $100.00 |
| | $475.00 |

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